Clinical Practice Guideline: **Acupuncture Services Medical Policy/Guideline**

Date of Implementation: **November 19, 2015**

Product: **Specialty**

Related Policies:

- CPG 12 Medical Necessity Decision Assist Guide for Rehabilitative Care
- CPG 30 Laser Therapy
- CPG 39 Direct Moxibustion
- CPG 48 Indirect Moxibustion
- CPG 89 Instrument-Assisted Soft Tissue Mobilization
- CPG 111 Patient Assessments: Medical Necessity Decision Assist Guideline for Evaluations and Re-evaluations For Dates of Service Effective January 1, 2021
- CPG 112 Exercise Treatment for Non-Specific Low Back Pain
- CPG 113 Exercise Treatment for Neck Pain
- CPG 121 Passive Physiotherapy Modalities
- CPG 133 Techniques and procedures not Widely Supported as Evidence-Based
- CPG 135 Physical Therapy Medical Policy Guideline
- CPG 155 Occupational Therapy Medical Policy Guidelines
- CPG 157 Lymphedema
- CPG 167 Therapeutic Massage
- CPG 175 Extraspinal Joint Manipulation, Mobilization Upper Extremities
- CPG 177 Extraspinal Joint Manipulation, Mobilization Lower Extremities
- CPG 272 Electric Stimulation for Pain, Swelling and Function in the Clinic Setting
- CPG 273 Superficial Heat and Cold
- CPG 274 Deep Heat Modalities
- CPG 298 Telehealth Services and Phone-based Evaluation / Assessment and Management Services
- QM 20 Facility Standards

CPG 264 Revision 16 – S
Acupuncture Services Medical Policy/Guideline
Revised – August 15, 2023
To CHSO for review and approval 08/15/2023
CHSO reviewed and approved 08/15/2023
To CQT for informational review 09/11/2023
CQT reviewed as informational 09/11/2023
To QIC for informational review 10/03/2023
QIC reviewed as informational 10/03/2023
To QOC for review and adoption 10/19/2023
QOC reviewed and adopted 10/19/2023

TABLE OF CONTENTS

(CTRL+Click on Section Heading to Follow Link)

DESCRIPTION OF THIS CLINICAL PRACTICE GUIDELINE

This document addresses Acupuncture services which may be delivered by an Acupuncture provider acting within the scope of a professional license. This document also addresses the processes associated with Medical Necessity Determinations performed by American Specialty Health (ASH) Clinical Quality Evaluators (CQEs) on Acupuncture services submitted for review.

The availability of coverage for Acupuncture services will vary by benefit design as well as by State and Federal regulatory requirements. Benefit plans may include a maximum allowable Acupuncture benefit, either in duration of course of treatment, number of visits, conditions covered, or type of services covered. When the maximum allowable benefit is exhausted or if the condition or service is not covered, coverage will no longer be provided even if the medical necessity criteria described below are met.

GUIDELINES

1. PROVIDERS OF ACUPUNCTURE SERVICES

Covered, medically necessary Acupuncture services must be delivered by a qualified acupuncture provider acting within the scope of their license as regulated by the Federal and State governments. Only those healthcare practitioners who hold an active license, certification, or registration with the applicable state board or agency may provide such services.

Aides and other non-qualified personnel are limited to the provision of non-skilled services such as preparing the individual, treatment area, equipment, or supplies.

2. ACUPUNCTURE SERVICES

2.1 Medically Necessary

For individuals not covered by Medicare, Acupuncture Services are considered medically necessary for treatment of any of the following:

- Tension-type Headache; Migraine Headache with or without Aura;
- Hip or Knee Joint Pain associated with Osteoarthritis (OA);
- Other Extremity Joint Pain associated with OA or mechanical irritation/inflammation when chronic and unresponsive to standard medical care;
- Other Pain Syndromes involving the joints and associated soft tissues;
- Musculoskeletal Cervical Spine, Thoracic Spine, and Lumbar Spine Pain;
- Nausea Associated with Pregnancy (only when co-managed);
- Post-Operative Nausea/Vomiting (generally within the first 24 hours after surgery) or Post-Discharge Nausea/Vomiting (generally within a few days after post-operative discharge); (only when co-managed);

- Nausea Associated with Chemotherapy; (only when co-managed).

AND when ALL of the following criteria are met

1 The services are delivered by a qualified provider of acupuncture services; and
2 The services require the judgment, knowledge, and skills of a qualified provider of acupuncture services due to the complexity and sophistication of the therapy and the clinical condition of the individual; and
3 The service is aimed at treatment of disorders for which coverage is available; and
4 The service is for conditions that require the unique knowledge, skills, and judgment of an acupuncture provider for education and training of the patient that is part of an active skilled plan of treatment; and
5 There is a clinically supported expectation that the service will result in a clinically significant level of functional improvement within a **reasonable and predictable period of time***; and
6 An individual's function could not reasonably be expected to continue to be sustained or improved without continued care as the individual gradually resumes normal activities; and
7 The documentation objectively verifies progressive functional improvement over specific time frames and clinically justifies the initiation of continuation of acupuncture services; and
8 There are no diagnostic red flags[1] or red flags are present and being addressed appropriately, including, as needed, co-management:
   - Examples of red flags may include but are not limited to: new or progressing neurological deficits; history of malignancy; long term steroid use; sudden weight loss; and
9 Any present yellow flags[2] are being evaluated and managed appropriately:
   - Examples of yellow flags may include but are not limited to: fear-avoidance behaviors; low self-efficacy; delayed return to work; and
10 There are no absolute contraindications present including, but not limited to:
   - The use of acupuncture with patients who have uncontrolled movements;

Reasonable and predictable period of time: The specific time frames for which one would expect practical functional improvement is dependent on various factors A reasonable trial of care to determine the patient's potential for improvement in or restoration of function is generally up to 4 weeks and is influenced by the patient's condition; clinical evaluation findings; stage of the condition (acute, sub-acute, chronic); severity of the condition; and patient-specific elements (age, gender, past and current medical history, family history, and any relevant psychosocial factors).

[1] *Red Flag(s): Signs and symptoms presented through history or examination/assessment that warrant more detailed and immediate medical assessment and/or intervention.*

[2] *Yellow Flag(s): Adverse prognostic indicators with a psychosocial predominance associated with chronic pain and disability. Yellow flags signal the potential need for more intensive and complex treatment and/or earlier specialist referral.*

- Needling of an edematous limb at risk of lymphedema. (Note: Placing an acupuncture needle in a limb at risk of, or exhibiting lymphedema is *absolutely contraindicated*)
- Needling of areas of spinal instability where relaxation of the surrounding muscles could potentially give rise to spinal cord compression;
- Needling of scars, keloids, recent wounds or skin with sensory deficit;
- Needling umbilicus area; infant fontanelles; area of breast; or implants/artificial joints;
- Hemophilia/hemorrhagic diseases; neutropenia, thrombocytopenia;
- Severe psychotic or other emotional conditions precluding patient cooperation and safety;
- Intoxication with alcohol, prescription medications or illicit drugs;
- Mechanical obstruction (i.e., foreign body in throat, bowel obstruction);
- Clear indications for surgical intervention (i.e., fractures, bleeding wounds);
- Fulminant infections/sepsis; acute wounds; burns at needle site;
- Damaged or prosthetic heart valves; history of endocarditis;
- Treatment that would cause harm by delaying other diagnosis or treatment;
- Electric stimulation with internal automatic defibrillator, or other implanted electronic devices: and

11 Any relative contraindications for acupuncture or electro-acupuncture therapy have been addressed and managed appropriately. Relative contraindications may include but are not limited to: anticoagulant therapy; seizure disorders; diabetes; skin conditions of concern in the area of needling or overall poor skin condition that might preclude needling; acute cerebrovascular accident; cancer (e.g., tumors local to area of needling or related systemic conditions such as thrombocytopenia); and

12 Treatment planning and outcomes meet the criteria defined below.

2.2 Not Medically Necessary

1. Acupuncture for any conditions other than those noted above is generally considered **not medically necessary.**
2. Maintenance care (e.g., elective care, wellness care) is considered **not** medically necessary and is often a specific benefit exclusion.
3. Acupuncture services are considered **not** medically necessary if **any** of the following is determined:
   a. The service is not aimed at treatment of disorders for which coverage is available.
   b. The service is for conditions for which therapy would be considered routine educational, training, conditioning, or fitness. This includes treatments or activities that require only routine supervision.

c. The expectation does **not** exist that the service(s) will result in a clinically significant improvement in the level of functioning within a reasonable and predictable period of time (up to 4 weeks).
    - If function could reasonably be expected to improve as the individual gradually resumes normal activities, then the service is considered **not** medically necessary.
    - If an individual's expected restoration potential would be insignificant in relation to the extent and duration of the service required to achieve such potential, the service(s) would be considered **not** medically necessary.
    - The documentation fails to objectively verify functional progress over a reasonable period of time (up to 4 weeks).
    - The patient has reached maximum therapeutic benefit.

d. A passive modality is **not** preparatory to other skilled treatment procedures or is not necessary in order to provide other skilled treatment procedures safely and effectively.

e. A passive modality has insufficient published evidence to support a clinically meaningful physiologic effect on the target tissue or improve the potential for a positive response to care for the condition being treated.

f. Services do **not** require the skills of a qualified provider of acupuncture services. Examples include but are not limited to:
    - Practitioner recommended activities and services that can be practiced independently and can be self-administered safely and effectively.
    - Home exercise programs that can be performed safely and independently to continue therapy without skilled supervision.
    - Activities for the general health and welfare of the individual such as:
        - General exercises (basic aerobic, strength, flexibility, or aquatic programs) to promote overall fitness/conditioning.
        - Services/programs for the primary purpose of enhancing or returning to athletic or recreational sports.
        - Massages and whirlpools for relaxation.
        - General public education/instruction sessions.

g. Reevaluations or assessments of a patient's status that are not separate and distinct services from those work components included within the acupuncture services Current Procedural Terminology (CPT) codebook codes. (See chart below)

h. Reevaluations or assessments of a patient's status that are not necessary to continue a course of therapy nor related to a new condition, new or changed health status for which the evaluation will likely result in a change in the treatment plan.

i. The treatments/services are **not** supported by and are **not** performed in accordance with peer-reviewed literature as documented in appliable ASH CPGs or other literature accepted by ASH Clinical Quality committees.

4. The following treatments are considered not medically necessary because they are educational, or training in nature. In addition, these treatments/programs may be specifically excluded under benefit plans:
   - Back school.
   - Group therapy (because it is not one-on-one, individualized to the specific patient's needs).
   - Vocational rehabilitation programs and any program or evaluation with the primary goal of returning a patient to work.
   - Work hardening programs.
   - Nutrition wellness education or similar wellness interventions.
5. The use of therapeutic magnets as a replacement for acupuncture needling services is not considered medically necessary. Magnet therapy is scientifically unproven for the treatment of pain, including when it is applied to acupuncture points. (*CPG 133 Techniques and procedures not Widely Supported as Evidence-Based and CPG 54 -Magnet Therapy - Static*).

2.3 Co-Management Requirements

Conditions that require medical co-management in order for treatment with acupuncture to be considered medically necessary include:

- Paralyses/Plegias
- Abdominal/Pelvic Pain
- Nausea/Vomiting
- Pregnancy
- Post-Surgical Conditions
- Ear/Eye Pain
- Cancer
- Masses
- Pain Related to Other/Systemic Conditions (e.g., Ankylosing Spondylitis, Human Immunodeficiency Virus (HIV), Multiple Sclerosis, Chest Pain).

Children 3 years of age and under:

Evidence of co-management with a medical provider must be documented for all conditions before the medical necessity review (MNR) can be completed. Documentation only that the child has a medical provider is not adequate.

Children 4-11 years of age:
Co-management with the child's medical provider is required. If documentation of co-management is not provided, response codes may be used as appropriate with medical necessity review to notify the acupuncture provider of the need to report the co-management information on the next medical necessity review submission. Documentation only that the child has a medical provider is not adequate.

The main objective of co-management requirements for children receiving acupuncture is to ensure the medical provider is aware of the child's condition, knows that acupuncture treatment is being sought, and has had the opportunity to coordinate care as needed.

Verification of medical necessity is required after the initial treatment/visit for all children under 12 years of age.

2.4 Medical Referral for Acupuncture

If acupuncture services are part of a referral-required program, they may be considered medically necessary only if the patient history, physical exam findings, diagnosis and treatment plan are consistent with the diagnosis provided by the referring physician.

3. CURRENT PROCEDURAL TERMINOLOGY (CPT) CODES AND DESCRIPTIONS FOR ACUPUNCTURE

CPT Code	Description
97810	Acupuncture, 1 or more needles; without electrical stimulation, initial 15 minutes of personal one-on-one contact with the patient
97811	Acupuncture, 1 or more needles; without electrical stimulation, each additional 15 minutes of personal one-on-one contact with the patient, with re-insertion of needle(s) (List separately in addition to code for primary procedure)
97813	Acupuncture, 1 or more needles; with electrical stimulation, initial 15 minutes of personal one-on-one contact with the patient
97814	Acupuncture, 1 or more needles; with electrical stimulation, each additional 15 minutes of personal one-on-one contact with the patient, with re-insertion of needle(s) (List separately in addition to code for primary procedure)

In addition to the CPT codes above, the following are covered for Center for Medicare and Medicaid Services (CMS) Acupuncture Chronic Low Back Pain programs. These CPT codes may be covered under other benefit plans. Check the applicable client summary for further information.

CPT Code	Description
20560	Needle insertion(s) without injection(s); 1 or 2 muscle(s)
20561	Needle insertion(s) without injection(s); 3 or more muscles

3.1 General CPT Guidelines for Acupuncture

1. Only one CPT code may be reported for each 15-minute increment.

2. Only one initial acupuncture code is reported per date of service as these services include both the treatment, set-up, and evaluation necessary to identify the specific acupuncture service(s) necessary for the patient. Therefore, when reporting this service, only one initial code is reported per date of service to identify the complete initial service provided.
3. For the initial increment, either code 97810***, or*** code 97813 for the initial 15 minutes of personal one-on-one contact with the patient, should be reported.

4. For each additional increment of "personal one-on-one contact with the patient" performed, either 97811 or 97814 is reported, depending on the use or non-use of electrical stimulation during that increment.

5. Re-insertion of the needle(s) is required for the use of add-on codes 97811 and 97814.

6. “Reinsertion” does not imply removing and replacing the same needles as would be contraindicated by related guidelines.

7. Acupuncture services performed without electrical stimulation and with electrical stimulation may be reported at the same session, provided separate 15-minute increments are spent performing each of the services.

8. Acupuncture is reported based on 15-minute increments of personal (face-to-face) contact with the patient and not the duration of acupuncture needle(s) retention.

9. One or two 15-minute episodes of acupuncture would be the most common pattern of practice and CPT code usage. More than two CPT codes would require documentation of special circumstances necessitating that level of acupuncture treatment.

10. Evaluation and management (E/M) services may be reported separately, by appending modifier -25. Significant, separately identifiable evaluation and management service by the same provider on the same day of the procedure or other service may be utilized, if the patient's condition requires a significant separately identifiable E/M service, above and beyond the usual preservice and post-service work associated with the acupuncture services. The time of the E/M service is not included in the time of the acupuncture service.

ACUPUNCTURE ADJUNCTIVE THERAPIES

Therapies may be used as adjuncts to, but not independently of, needle acupuncture. Adjunctive therapies must only be performed on the same date of service as needle acupuncture. Depending upon benefit design therapies may include, but are not limited to:

CPT Code	Description
97010	Application of a modality to one or more areas; hot or cold packs
97014	Application of a modality to one or more areas; electrical stimulation (unattended)
97018	Application of a modality to one or more areas; paraffin bath
97022	Application of a modality to one or more areas; whirlpool
97024	Application of a modality to one or more areas; diathermy (e.g., microwave)
97026	Application of a modality to one or more areas; infrared
97032	Application of a modality to one or more areas; electrical stimulation (manual), each 15 minutes
97034	Application of a modality to one or more areas; contrast baths, each 15 minutes
97035	Application of a modality to one or more areas; ultrasound, each 15 minutes
97039	Unlisted modality (specify type and time if constant attendance)*

CPT Code	Description
97110	Therapeutic procedure, one or more areas, each 15 minutes; therapeutic exercises to develop strength and endurance, range of motion and flexibility
97124	Therapeutic procedure, one or more areas, each 15 minutes; massage, including effleurage, petrissage and/or tapotement (stroking, compression, percussion)
97139	Unlisted therapeutic procedure (specify)*
97140	Manual therapy techniques (e.g., mobilization/manipulation, manual lymphatic drainage, manual traction), one or more regions, each 15 minutes
97530	Therapeutic activities, direct (one-on-one) patient contact (use of dynamic activities to improve functional performance), each 15 minutes
97799	Unlisted physical medicine/rehabilitation service or procedure*
G0283	Electrical Stimulation (unattended), to one or more areas for indication(s) other than wound care, as part of a therapy plan of care

*Procedures listed under the "unlisted" CPT codes (97039, 97139 & 97799) will not be covered without documentation of medical necessity.

4.1 Adjunctive Modalities

The CPT codebook defines a modality as "any physical agent applied to produce therapeutic changes to biologic tissue; includes but is not limited to thermal, acoustic, light, mechanical, or electric energy." Modalities may be supervised, which means that the application of the modality does not require direct one-on-one patient contact by the provider; or modalities may involve constant attendance, which indicates that the modality requires direct one-on-one patient contact by the provider.

Supervised modalities are untimed therapies. Untimed therapies are usually reported only once for each date of service regardless of the number of minutes spent providing this service or the number of body areas to which they were applied. Untimed services billed as more than one unit will require significant documentation to justify treatment greater than one session per day. Examples of supervised modalities include:

- Hot or cold packs
- Unattended electrical stimulation
- Paraffin bath

- Infrared light

Modalities that require constant attendance, are timed, and reported in 15-minute increments (one unit) regardless of the number of body areas to which they are applied. Examples of modalities that require constant attendance include:

- Ultrasound
- Massage
- Manual electrical stimulation

4.2 Adjunctive Therapeutic Procedures

The CPT codebook defines therapeutic procedures as "A manner of effecting change through the application of clinical skills and/or services that attempt to improve function." Therapeutic procedures that may be utilized by acupuncture providers require direct (one-on-one) patient contact by the provider, are timed therapies, and must be reported in units of 15-minute increments. Only the actual time that the acupuncture provider is directly working with the patient performing exercises/activities, instruction, or assessments is counted as treatment time. The time that the patient spends not being treated because of a need for rest or equipment set up is not considered treatment time. Any exercise/activity that does not require, or no longer requires, the skilled assessment and intervention of a health care practitioner is not considered a medically necessary therapeutic procedure. Exercises often can be taught to the patient or a caregiver as part of a home/self-care program. Examples of therapeutic procedures that require the provider to have direct (one-on-one) patient contact include:

- Therapeutic exercises
- Manual therapy (e.g., soft tissue mobilization)

4.3 Documentation Requirements to Substantiate Medical Necessity of Therapeutic Modalities and Procedures

Proper and sufficient documentation is essential to establish the clinical necessity and effectiveness of each modality and procedure, aid in the determination of patient outcomes management, and support continuity of patient care. At a minimum, documentation is required for every treatment day and for each therapy performed. Each daily record should include: the date of service, the name of each modality and/or procedure performed, the parameters for each modality (e.g., amperage/voltage, location of pads/electrodes), area of treatment, total treatment time spent for each therapy (mandatory for timed services), the total treatment time for each date of service, and the identity of the person(s) providing the services. Failure to properly identify and sufficiently document the parameters for each therapy on a daily progress note may result in an adverse determination (partial approval or denial).

4.4 Passive Care and Active Care

Generally, passive modalities are used to manage the acute inflammatory response, pain, and/or muscle tightness or spasm in the early stages of musculoskeletal and related condition management. They are most effective during the acute phase of treatment. The use of passive modalities in the treatment of sub-acute or chronic conditions beyond the acute inflammatory response time frame is generally considered not medically necessary unless there is an exacerbation. The use of passive modalities is generally considered not medically necessary unless they are preparatory and essential to the safe and effective delivery of other skilled treatment procedures (e.g., therapeutic exercise training, etc.). Prolonged reliance on passive modalities is not supported by the clinical literature.

A "passive therapy" is a procedure applied by a clinical practitioner without active engagement or movement of the patient (e.g., ultrasound, hot packs).

The selection of a passive modality should be based on an understanding of the known physiologic effects of the modality, contraindications, the stage of injury and/or tissue healing, anatomical location to be treated, patient specific conditions and the likelihood of the therapy to enhance recovery or facilitate treatment with active therapeutic procedures. Use of more than two (2) modalities on each visit date is unusual and should be justified in the documentation.

Transition from passive modalities to active treatment procedures should be timely and evidenced in the medical record, including instructions on self/home care. Patients should progress from active procedures requiring the supervision of a skilled practitioner to a self-directed home activity program as soon as possible.

Modalities chosen to treat the patient's symptoms/conditions should be selected based on the most effective and efficient means of achieving the patient's functional goals. Seldom should a patient require more than one (1) or two (2) modalities to the same body part during the therapy session. Use of more than two (2) modalities on each visit date is unusual and should be justified in the documentation.

When the symptoms that required the use of certain modalities begin to subside and function improves, the medical record should reflect the discontinuation of those modalities, to determine the patient's ability to self-manage any residual symptoms. As the patient improves, the medical record should reflect a progression from passive therapies to an active care program (e.g., therapeutic exercise). In all cases, the patient and/or caregiver should be taught aspects of self-management of his/her condition from the start of therapy.

ASH maintains a broad library of Clinical Practice Guidelines that address the medical necessity criteria of commonly performed physical medicine and rehabilitative services. These include, but are not limited to:

- CPG 121 Passive Physiotherapy Modalities
- CPG 135 Physical Therapy Medical Policy Guideline
- CPG 167 Therapeutic Massage
- CPG 272 Electric Stimulation for Pain, Swelling and Function in the Clinic Setting
- CPG 273 Superficial Heat and Cold
- CPG 274 Deep Heat Modalities

4.5 Treatment Interventions

Below are descriptions and medical necessity criteria, as applicable, for different treatment interventions, including specific modalities and therapeutic procedures associated with Acupuncture services. This material is for informational purposes only and is not indicative of coverage, nor is it an exhaustive list of services provided.

Hot/Cold Packs

Hot packs increase blood flow, relieve pain, and increase flexibility. Cold packs decrease blood flow to an area for reduction of pain and swelling. They may be considered medically necessary for musculoskeletal conditions that include significant pain and or swelling.

Paraffin Bath

This modality uses hot wax for application of heat. It is indicated for use to relieve pain and increase range of motion of extremities (typically wrists and hands) in post-surgical patients or patients with chronic joint dysfunction

Infrared Light Therapy

Infrared light therapy is a form of heat therapy used to increase circulation to relieve muscle spasm. Other heating modalities are considered superior to infrared lamps and should be considered unless there is a contraindication to those other forms of heat. Utilization of the Infrared light therapy CPT code is not appropriate for low level laser treatment.

Electrical Stimulation

Various types and frequencies of electrical stimulation are used to relieve pain, reduce swelling, and improve muscle function.

Ultrasound

This modality provides deep heating and possibly micro-massage to a localized area through high frequency sound wave application. Ultrasound may be considered medically necessary to relieve pain and improve healing.

Therapeutic Exercises

Therapeutic exercise includes instruction, feedback, and supervision of a person in an exercise program specific to their condition. Therapeutic exercise may be considered medically necessary to restore/develop strength, endurance, range of motion and flexibility which has been lost or limited because of a disease or injury. Exercising done by the patient within a clinic facility or other location (e.g., home; gym) without a provider present and supervising would be considered not medically necessary.

Precautions and Contraindications to Therapeutic Modalities and Procedures

1. The use of thermotherapy is contraindicated for the following:

- Recent or potential hemorrhage
- Thrombophlebitis
- Impaired sensation
- Impaired mentation
- Malignant tumor
- IR irradiation of the eyes

Precautions for use of thermotherapy include:

- Acute injury or inflammation
- Pregnancy
- Impaired circulation
- Poor thermal regulation
- Edema
- Cardiac insufficiency
- Metal in the area
- Over an open wound
- Over areas where topical counterirritants have recently been applied
- Demyelinated nerve

2. The use of cryotherapy is contraindicated for the following:

- Cold hypersensitivity
- Cold intolerance
- Cryoglobulinemia
- Paroxysmal cold hemoglobinuria
- Raynaud disease or phenomenon
- Over regenerating peripheral nerves
- Over an area with circulatory compromise or peripheral vascular disease

Precautions for cryotherapy include:

- Over the superficial branch of a nerve
- Over an open wound
- Hypertension
- Poor sensation or mentation

3. The use of immersion hydrotherapy is contraindicated for the following:

- Cardiac instability
- Confusion or impaired cognition
- Maceration around a wound
- Bleeding
- Infection in the area to be immersed
- Bowel incontinence
- Severe epilepsy
- Suicidal patients

Precautions for full body immersion in hot or very warm water include:

- Pregnancy
- Multiple Sclerosis
- Poor thermal regulation

4. Contraindications for Traction include:

- Where motion is contraindicated
- Acute injury or inflammation
- Joint hypermobility or instability
- Peripheralization of symptoms with traction
- Uncontrolled hypertension

Precautions for Traction include:

- Structural diseases or conditions affecting the tissues in the area to be treated (e.g., tumor, infection, osteoporosis, RA, prolonged systemic steroid use, local radiation therapy)
- When pressure of the belts may be hazardous (e.g., with pregnancy, hiatal hernia, vascular compromise, osteoporosis)
- Displaced annular fragment
- Medial disc protrusion
- When severe pain fully resolves with traction
- Claustrophobia or other psychological aversion to traction
- Inability to tolerate prone or supine position

- Disorientation

Additional precautions for cervical traction:

- TMJ problems
- Dentures

5. The use of thermal shortwave diathermy (SWD) is contraindicated for the following

- Any metal in the treatment area or on/in the body.
- Malignancy
- Eyes
- Testes
- Growing epiphyses

Contraindications for all forms of SWD:

- Implanted or transcutaneous neural stimulators including cardiac pacemakers
- Pregnancy

Precautions for all forms of SWD:

- Near electronic or magnetic equipment
- Obesity
- Copper-bearing intrauterine contraceptive devices

6. Contraindications for use of Electrical Currents:

- Demand pacemakers, implantable defibrillator, or unstable arrhythmia
- Placement of electrodes over carotid sinus
- Areas where venous or arterial thrombosis or thrombophlebitis is present
- Pregnancy – over or around the abdomen or low back

Precautions for electrical current use:

- Cardiac disease
- Impaired mentation
- Impaired sensation
- Malignant tumors
- Areas of skin irritation or open wounds

7. Contraindications to the use of ultrasound include:

- Malignant tumor
- Pregnancy
- Central Nervous Tissue

- Joint cement
- Plastic components
- Pacemaker or implantable cardiac rhythm device
- Thrombophlebitis
- Eyes
- Reproductive organs

Precautions for Ultrasound include:

- Acute inflammation
- Epiphyseal plates
- Fractures
- Breast implants

The use of electrical muscle stimulation, SWD, thermotherapy, cryotherapy, ultrasound, laser/light therapy, immersion hydrotherapy, and mechanical traction with pediatric patients is contraindicated if the patient cannot provide the proper feedback necessary for safe application.

In addition to the contraindications listed above, there are a wide range of services which are considered unproven, pose a significant health and safety risk, are scientifically implausible and/or are not widely supported as evidence based. Such services would be considered not medically necessary and include, but are not limited to:

- Axial/Spinal decompression
- Dry needling
- Laser therapy
- Manual muscle testing to diagnosis non-neuromusculoskeletal conditions
- Microcurrent Electrical Nerve Stimulation (MENS)
- Other unproven procedures (see the *Techniques and Procedures Not Widely Supported as Evidence-Based (CPG 133 – S)* clinical practice guideline for complete list)

4.6 Redundant Therapeutic Effects and Services by Different Healthcare Practitioners/Specialties

Certain therapeutic modalities and procedures are considered redundant in nature, and it would be inappropriate to provide these services to the same body region during the same treatment session. This includes treatments, such as but not limited to:

- More than one heating modality
- Massage therapy and myofascial release

Duplicate services provided by different healthcare practitioners/specialties for the same condition(s) are considered **not** medically necessary. When patients receive acupuncture services, physical therapy services, occupational therapy services, or other healthcare specialty services for the same condition(s), the healthcare practitioners should provide different treatments that reflect each healthcare discipline's unique perspective on the patient's impairments and functional deficits and not duplicate the same treatment. Each healthcare specialty practitioner must also have separate and distinct evaluations, treatment plans, and goals.

5. CLINICAL DOCUMENTATION

For more information, see the *Medical Record Maintenance and Documentation Practices (CPG 110 – S)* clinical practice guideline.

Medical record keeping is an essential component of patient evaluation and management. Medical records should be legible and should contain, at a minimum, sufficient information to identify the patient, support the diagnosis, justify the treatment, accurately document the results, indicate advice and cautionary warnings provided to the patient and provide sufficient information for another practitioner to assume continuity of the patient's care at any point in the course of treatment. Good medical record keeping improves the likelihood of a positive outcome and reduces the risk of treatment errors. It also provides a resource to review cases for opportunities to improve care, provides evidence for legal records, and offers necessary information for third parties who need to review and understand the rationale and type of services rendered (e.g., medical billers and auditors/reviewers).

Outcome measures are important in determining effectiveness of a patient's care. The use of standardized tests and measures early in an episode of care establishes the baseline status of the patient, providing a means to quantify change in the patient's functioning. Outcome measures provide information about whether predicted outcomes are being realized. When comparing follow-up with baseline outcome metrics does not demonstrate minimal clinically important difference (MCID) (minimal amount of change in a score of a valid outcome assessment tool) the treatment plan should be changed or be discontinued. Failure to use Functional Outcome Measures (FOMs) / Outcome Assessment Tools (OATs) may result in insufficient documentation of patient progress and may result in an adverse determination (partial approval or denial) of continued care.

5.1 Evaluation and Re-evaluation

As a best practice, all the following should be clearly described in the submitted records:

- Historical information including a clear description of the current complaint(s);
- Prior and current levels of function;
- Tests performed and the results (e.g., evaluation findings);

- Valid diagnosis(es);
- Therapeutic goals and treatment plan (e.g., specific treatments, number of office visits);
- Response to care, progress, and prognosis ; and
- Self – Care advice, including home exercise program.

An initial evaluation service is essential to determine whether any services that may be recommended by the evaluating practitioner are medically necessary, to determine if referral to another clinical setting or another type of evaluation is necessary, to gather baseline data, establish a treatment plan, and develop goals based on the data. The initial evaluation is usually completed in a single session. An evaluation is needed before implementing any acupuncture treatment. Initial evaluations include an Evaluation and Management (New Patient or Established Patient E/M) history and physical examination service and may be supported by, as necessary, imaging, laboratory studies, and/or other diagnostic tests and measures in accordance with scope of practice rules and regulations.

The acupuncture service CPT codes 97810 and 97813 include a brief interval history and examination of the patient's condition, as well as documentation of the patient's response to the treatment and any changes to goals or treatment plan. Routine use of E/M services is not medically necessary. A reevaluation is considered medically necessary following a trial of care to determine whether that care resulted in significant clinical improvement documenting the need to continue a course of therapy, there is need for referral to other healthcare practitioner(s)/specialist(s), or that discontinuance of treatment is warranted.
A reevaluation (an Established Patient E/M service) is considered medically necessary when all of the following conditions are met:

- The reevaluation exceeds the recurring routine assessment of patient status included in the work value of the Acupuncture CPT codes work-value; and
- The documentation of the reevaluation includes **all** of the following elements:
  - Evaluation of progress toward current goals; and
  - Professional judgment about continued care; and
  - Professional judgment about revising goals and/or treatment or terminating services; and
- Any **one** of the following indications is documented:
  - An exacerbation, a new condition(s), or new clinical findings.
  - Significant change in the patient's condition(s).
  - Failure to respond to the therapeutic interventions outlined in the current plan of care.

A reevaluation is considered **not** medically necessary once it has been determined that the patient has reached maximum therapeutic benefit from the services provided unless there is/are medically necessary reason(s) documented for the reevaluation service.

5.2 New and Established Patient Definitions

The CPT codebook provides the following definitions:

New Patient: Is one who **has not** received any professional services from the physician/qualified health care professional or another physician/qualified health care professional of the exact same special and subspecialty who belongs to the same group practice, within the past three (3) years.

Established Patient: Is one who **has** received professional services from the physician/qualified health care professional or another physician/qualified health care professional of the exact same specialty and subspecialty who belongs to the same group practice, within the past three (3) years.

5.3 Treatment Sessions

Acupuncture treatment can vary from acupuncture alone (CPT codes 97810, 97811, 97813, 97814) to the use of a variety of adjunctive modalities and procedures depending on the patient's condition, response to care and treatment tolerance. All services must be supported in the treatment plan and be based on an individual's medical condition. An acupuncture treatment session may include:

- A brief evaluation of the patient's progress and response to previous treatment(s);
- Acupuncture.
- Adjunctive modalities (e.g., moxa, Tui Na, hot/cold packs, therapeutic exercise);
- Recommendations for self-care and home management.
- Skilled reassessment of the individual's problems, plan, and goals as part of the treatment session.
- Coordination, communication, and documentation.
- Reevaluation, if there is a significant change in the individual's condition or there is a need to update and modify the treatment plan.

Documentation of treatment sessions should include at a minimum:

- Date of treatment.
- Subjective complaints and current status (including functional deficits and ADL restrictions).
- Description/name of each specific treatment intervention provided, including Acupuncture points used, total numbers of needles inserted and removed

    - The parameters for each therapy provided (e.g., voltage/amperage, pad/electrode placement, area of treatment, types of exercises/activities, and intended goal of each therapy);
    - Treatment time for each therapy and total treatment time per date of service;
- The patient's response to each service and to the entire treatment session;
- Any progress toward the goals in objective, measurable terms using consistent and comparable methods;
- Any changes to the plan of care;
- Recommendations for follow-up visit(s);
- Signature/electronic identifier, name and credentials of the treating clinician.

5.4 Duplicated / Insufficient Information

Entries in the medical record should be contemporaneous, individualized, appropriately comprehensive, and made in a chronological, systematic, and organized manner. Duplicated/nearly duplicated medical records (a.k.a. cloned records) are not acceptable. It is not clinically reasonable or physiologically feasible that a patient's condition will be identical on multiple encounters. (Should the findings be identical for multiple encounters, it would be expected that treatment would end because the patient is not making progress toward current goals.)

This includes, but is not limited to:

- Duplication of information from one treatment session to another (for the same or different patient[s]).
- Duplication of information from one evaluation to another (for the same or different patient[s]).

Duplicated medical records do not meet professional standards of medical record keeping and may result in an adverse determination (partial approval or denial) of those services.

The use of a system of record keeping that does not provide sufficient information (e.g., checking boxes, circling items from lists, arrows, travel cards with only dates of visit and listings). These types of medical record keeping may result in an adverse determination (partial approval or denial) of those services.

Effective and appropriate records keeping that meet professional standards of medical record keeping document with adequate detail a proper assessment of the patient's status, the nature and severity of his/her complaint(s) or condition(s), and/or other relevant clinical information (e.g., history, parameters of each therapy performed, objective findings, progress towards treatment goals, response to care, prognosis.).

5.5 Centers for Medicare and Medicaid Services (CMS)

For Medicare and Medicaid services, medical records keeping must follow and be in accordance with Medicare and any additional state Medicaid required documentation guidelines.

6. CLINICAL REVIEW PROCESS

Medical necessity evaluations require approaching the clinical data and scientific evidence from a global perspective and synthesizing the various elements into a congruent picture of the patient's condition and need for skilled treatment intervention. Clinical review decisions made by the CQEs are based upon the information provided by the treating practitioner in the submitted documentation and other related findings and information. Failure to appropriately document pertinent clinical information may result in adverse determinations (partial approval or denial) of those services. Therefore, thorough documentation of all clinical information that established the diagnosis/diagnoses and supports the intended treatment is essential.

6.1 Definition of Key Terminology used in Clinical Reviews

Elective/Convenience Services

Examples of elective/convenience services include: (a) preventive services; (b) wellness services; (c) services not necessary to return the patient to pre-illness/pre-injury functional status and level of activity; (d) services provided after the patient has reached MTB. (Elective/convenience services may not be covered through specific client or ASH benefits.)

Minimal Clinically Important Difference (MCID)

The MCID is the minimal amount of change in a score of a valid outcome assessment tool that indicates an actual improvement in the patient's function or pain. Actual significance of outcome assessment tool findings requires correlation with the overall clinical presentation, including updated subjective and objective examination/evaluation findings.

Maximum Therapeutic Benefit (MTB)

MTB is the patient's health status when the application of skilled therapeutic services has achieved its full potential (which may or may not be the complete resolution of the patient's condition.) At the point of MTB, continuation of the same or similar skilled treatment approach will not significantly improve the patient's impairments and function during this episode of care.

If the patient continues to have significant complaints, impairments, and documented functional limitations, one should consider the following:

- Altering the treatment regimen such as utilizing a different physiological approach to the treatment of the condition, or decreasing the use of passive care (modalities,

massage etc.) and increasing the active care (therapeutic exercise) aspects of treatment to attain greater functional gains.

- Reviewing self-management program including home exercise programs; and/or
- Referring the patient for consultation by another health care practitioner for possible co-management or a different therapeutic approach.

Preventive Services

Preventive services are designed to reduce the incidence or prevalence of illness, impairment, and risk factors, and to promote optimal health, wellness, and function. These services are not designed or performed to treat or manage a specific health condition. (Preventive services may or may not be covered under specific clients or through ASH benefits.)

Acute

The stage of an injury, illness, or disease, in which the presence of clinical signs and symptoms is less than six weeks in duration, typically characterized by the presence of one or more signs of inflammation or other adaptive response.

Sub-Acute

The stage of an injury, illness, or disease, in which the presence of clinical signs and symptoms is greater than six weeks, but not greater than twelve weeks in duration.

Chronic

The stage of an injury, illness, or disease, in which the presence of clinical signs and symptoms is greater than twelve weeks in duration.

Red Flag(s)

Signs and symptoms presented through history or examination/assessment that warrant more detailed and immediate medical assessment and/or intervention.

Yellow Flag(s)

Adverse prognostic indicators with a psychosocial predominance associated with chronic pain and disability. Yellow flags signal the potential need for more intensive and complex treatment and/or earlier specialist referral.

Co-Morbid Condition(s)

The presence of a concomitant condition, that has an unrelated pathology or disease process, but may inhibit, lengthen, or alter in some way the expected response to care.

6.2 Clinical Quality Evaluation

The goal of the CQEs during the review and decision-making process is to approve, as appropriate, those clinical services necessary to return the patient to pre-clinical/pre-morbid health status or stabilize a chronic condition, as supported by the documentation presented. The CQE is to evaluate if the documentation and other clinical information presented by the treating provider has appropriately substantiated the patient's condition and justifies the treatment plan that is presented.

Approval

ASH CQEs have the responsibility to approve appropriate care for all services that are medically necessary. The CQEs assess the clinical data supplied by the practitioner in order to determine whether submitted services and/or the initiation or continuation of care has been documented as medically necessary. The practitioner is accountable to document the medical necessity of all services submitted/provided. It is the responsibility of the peer CQE to evaluate the documentation in accordance with their training, understanding of practice parameters, and review criteria adopted by ASH through its clinical committees.

Partial Approval

Occurs when only a portion of the submitted services are determined to be medically necessary services. The partial approval may refer to a decrease in treatment frequency, treatment duration, number of therapies, or other services from the original amount/length submitted for review. This decision may be due to any number of reasons, such as:

- The practitioner's documentation of the history and exam findings are inconsistent with the clinical conclusion(s).
- The treatment dosage (frequency/duration) submitted for review is not supported by the underlying diagnostic or clinical features.
- The need to initiate only a limited episode of care in order to monitor the patient's response to care.

Additional services may be submitted and reviewed for evaluation of the patient's response to the initial trial of care. If the practitioner or patient disagrees with the partial approval of services, they may contact the CQE listed on their response form to discuss the case, submit additional documentation through the Reopen process, or submit additional documentation to appeal the decision through the clinical appeal process.

Non-approval / Denial

Occurs when none of the services submitted for review are determined to be medically necessary services. The most common causes for a non-approval/denial of all services are administrative or contractual in nature (e.g., ineligibility, reached plan benefit limits, non-coverage). Clinically, it is appropriate to deny continued/ongoing care if the patient's

condition(s) are not, or are no longer, responding favorably to the services being rendered by the treating practitioner, or the patient has reached maximum therapeutic benefit.

Additional / Continued Care

Approval of an additional treatment/services requires submission of additional information, including the patient's response to care and updated clinical findings. In cases where an additional course of care is submitted, the decision to approve additional treatment/services will be based upon the following criteria:

- The patient has made clinically significant progress under the initial treatment plan/program based on a reliable and valid outcome tool or updated subjective and objective examination findings.
- Additional clinically significant progress can be reasonably expected by continued treatment (The patient has not reached MTB or maximum medical improvement).
- There is no indication that immediate care/evaluation is required by other health care professionals.

Any exacerbation or flare-up of the condition that contributes to the need for additional treatment/services must be clearly documented.

Ancillary diagnostic procedures should be selected based on clinical history and examination findings that suggest the necessity to rule out underlying pathology or to confirm a diagnosis that cannot be verified through less invasive methods.

- Information is expected to directly impact the treatment/services and course of care.
- The benefit of the procedure outweighs the risk to the patient's health (short and long term).
- The procedure is sensitive and specific for the condition being evaluated (e.g., an appropriate procedure is utilized to evaluate for pathology).

The clinical information that the CQE expects to see when evaluating the documentation in support of the medical necessity of submitted treatment/services should be commensurate with the nature and severity of the presenting complaint(s), the scope of the services being requested, the scope of practice of the practitioner performing the services, and may include but is not limited to:

- History
- Physical examination/evaluation
- Documented treatment plan and goals
- Estimated time of discharge

In general, the initiation of care is warranted if there are no contraindications to the care, there is reasonable evidence to suggest the efficacy of the intervention, and the intervention is within the scope of services permitted by State or Federal law. The treatment submission

for a disorder is typically structured in time-limited increments depending on clinical presentation. Dosage (frequency and duration of service) should be appropriately correlated with clinical findings, potential complications/barriers to recovery and clinical evidence. When the practitioner discovers that a patient is nonresponsive to the applied interventions within a reasonable time frame, re-assessment and treatment modification should be implemented and documented. If the patient's condition(s) worsen, the practitioner should take immediate and appropriate action to discontinue or modify care and/or make an appropriate healthcare referral.

Services that do not require the professional skills of a practitioner to perform or supervise are not medically necessary. If a patient's recovery can proceed safely and effectively through a home exercise program or self-management program, services are not indicated or medically necessary.

6.3 Critical Factors During Clinical Reviews

The complexity and/or severity of historical factors, symptoms, examination findings, and functional deficits play an essential role to help quantify the patient's clinical status and assess the effectiveness of planned interventions over time. CQEs consider patient-specific variables as part of the medical necessity verification process. The entire clinical picture must be taken into consideration with each case evaluated based upon unique patient and condition characteristics.

Such variables may include, but not be limited to co-morbid conditions and other barriers to recovery, the stage(s) of the condition(s), mechanism of injury, severity of the symptoms, functional deficits, and exam findings, as well as social and psychological status of the patient and the available support systems for self-care. In addition, the patient's age, symptom severity, and the extent of positive clinical findings may influence duration, intensity, and frequency of services approved as medically necessary. For example:

- Severe symptomatology, exam findings, and/or functional deficits may require more care overall (e.g., longer duration, more services per encounter than the average); these patients may require a higher frequency of care; but may require short-term trials of care initially to assess the patient response to care.
- Less severe symptomatology, exam findings and/or functional deficits usually require less care overall (e.g., shorter duration, fewer services per encounter, and frequency of encounters than the average); but may allow for less oversight and a longer initial trial of care.
- As patients age, they may have a slower response to care and this may affect the approval of a trial of care.

- Because pediatric patients (under the age of 12) have not reached musculoskeletal maturity, it may be necessary to modify the types of therapies approved as well as shorten the initial trial of care.
- Complicating and/or co-morbid condition factors vary depending upon individual patient characteristics, the nature of the condition/complaints, historical and examination elements, and may require appropriate coordination of care and/or more timely re-evaluations.

The following are examples of the factors CQEs consider when verifying the medical necessity of rehabilitative services for musculoskeletal conditions and pain disorders.

6.4 General Factors

Multiple patient-specific historical and clinical findings may influence clinical decisions, such as but not limited to:

- Red flags
- Yellow flags (psychosocial factors)
- Co-morbid conditions (e.g., diabetes, inflammatory conditions, joint instability)
- Age (older or younger)
- Non-compliance with treatment and/or self-care recommendations
- Lack of response to appropriate care
- Lifestyle factors (e.g., smoking, diet, stress, deconditioning)
- Work and recreational activities
- Pre-operative/post-operative care
- Medication use (type and adherence)

Nature of Complaint(s)

- Acute and severe symptoms
- Functional testing results that display severe disability/dysfunction
- Pain that radiates below the knee or elbow (for spinal conditions)

History

- Trauma resulting in significant injury or functional deficits
- Pre-existing pathologies/surgery(ies)
- Congenital anomalies (e.g., severe scoliosis)
- Recurring exacerbations
- Prior episodes (e.g., >3 for spinal conditions)
- Multiple new conditions which introduce concerns regarding the cause of these conditions

Examination

- Severe signs/findings
- Results from diagnostic testing that are likely to impact coordination of care and response to care (e.g., fracture, joint instability, neurological deficits)

Assessment of Red Flags

At any time the patient is under care, the practitioner is responsible for seeking and recognizing signs and symptoms that require additional diagnostics, treatment/service, and/or referral. A careful and adequately comprehensive history and evaluation in addition to ongoing monitoring during the course of treatment is necessary to discover potential serious underlying conditions that may need urgent attention. Red flags can present themselves at several points during the patient encounter and can appear in many different forms. If a red flag is identified during a medical necessity review, the CQE should communicate with the provider of services as soon as possible by telephone and/or through standardized communication methods. When a red flag is identified, the CQE may not approve services and recommend returning the patient back to the referring healthcare practitioner or referring the patient to other appropriate health care practitioner/specialist with the measure of urgency as warranted by the history and clinical findings.

Due to the rarity of actual red flag diagnoses in clinical practice, it is emphasized that the practitioner does not need to perform expensive or invasive diagnostic procedures (e.g., x-ray, advanced imaging, laboratory studies) in the absence of suspicious clinical characteristics. Important red flags and events as well as the times during the clinical encounter at which they are likely to appear include but may not be limited to:

Past or Current History

- Personal or family history of cancer
- Current or recent urinary tract, respiratory tract, or other infection
- Anticoagulant therapy or blood clotting disorder
- Metabolic bone disorder (osteopenia and osteoporosis)
- Unintended weight loss
- Unexplained dizziness or hearing loss
- Trauma with skin penetration
- Immunosuppression (e.g., AIDS/ARC)

Present Complaint

- Writhing or cramping pain
- Precipitation by significant trauma
- Pain that is worse at night or not relieved by any position
- Suspicion of cerebrovascular compromise

- Symptom's indicative of progressive neurological disorder

Physical Examination/Assessment

- Inability to reproduce symptoms of musculoskeletal diagnosis or complaints
- Pulsing abdominal mass
- Fever, chills, or sweats without other obvious source
- New or recent neurologic deficit (special senses, sensory, language, and motor)
- Signs of carotid/vertebrobasilar insufficiency
- Uncontrolled hypertension
- Signs of nutritional deficiency
- Signs of allergic reaction requiring immediate attention
- Abuse/neglect
- Psychological distress

Pattern of Symptoms Not Consistent with Benign Disorder

- Chest tightness, difficulty breathing, chest pain
- Headache of morbid proportion
- Rapidly progressive neurological deficit
- Significant, unexplained extremity weakness or clumsiness
- Change in bladder or bowel function
- New or worsening numbness or paresthesia
- Saddle anesthesia
- New or recent bilateral radiculopathy

Lack of Response to Appropriate Care

- History of consultation/care from a series of practitioners or a variety of health care approaches without resolving the patient's complaint
- Unsatisfactory clinical progress, especially when compared to apparently similar cases or natural progression of the condition
- Signs and symptoms that do not fit the normal pattern and are not resolving

Assessment of Yellow Flags

When yellow flags are present, clinicians need to be vigilant for deviations from the normal course of illness and recovery. Examples of yellow flags include depressive symptoms, injuries still in litigation, signs and symptoms not consistent with pain severity, and behaviors incongruent with underlying anatomic and physiologic principles.

If a yellow flag is identified during a medical necessity review, the reviewer will communicate with the provider of services as soon as possible by telephone and/or through standardized communication methods. CQE may recommend returning the patient back to

the referring healthcare practitioner or referring the patient to other health care practitioner/specialist as appropriate.

Assessment of Historical Information

The following factors are assessed in review and determination if the services are medically necessary:

- The mechanism of onset and date of onset are congruent with the stated condition's etiology.
- The patient's past medical history and response to care do not pose contraindication(s) for the services submitted for review.
- The patient's past medical history of pertinent related and unrelated conditions does not pose contraindication(s) for the services submitted for review.
- The patient's complaint(s) have component(s) that are likely to respond favorably to services submitted for review.
- Provocative and palliative factors identified on examination indicate the presence of a musculoskeletal condition as expected per diagnosis(es) or complaints, or as consistent with other type of diagnosis(es).
- The patient's severity of limitations to activities of daily living (ADLs) are appropriate and commensurate for the presence of the condition(s) or disorder(s).
- The quality, radiation, severity, and timing of pain are congruent with the documented condition(s) or disorder(s).
- The patient's past medical history of having the same or similar condition(s) indicates a favorable response to care.
- The absence or presence of co-morbid condition(s) may or may not present absolute or relative contraindications to care.

Assessment of Examination Findings

- The exam procedures, level of complexity, and intensity are appropriate for the patient's complaint(s) and historical findings.
- Physical examination findings are current, clearly defined, qualified, and quantified, including the nature, extent, severity, character, professional interpretation, and significance of the finding(s) in relation to the patient's complaint(s) and diagnosis(es).
- Exam findings provide evidence justifying the condition(s) is/are likely to respond favorably to services submitted for review.
- Exam findings provide a reasonable and reliable basis for the stated diagnosis(es).
- Exam findings provide a reasonable and reliable basis for treatment planning; accounting for variables such as age, sex, physical condition, occupational and recreational activities, co-morbid conditions, etc.

- The patient's progress is being appropriately monitored each visit (as noted within daily chart notes and during periodic re-exams) to ensure that acceptable clinical progress is realized.

Assessment of Treatment / Treatment Planning

- Treatment dosage (frequency and duration of service) is appropriately correlated with the nature and severity of the subjective complaints, potential complications/barriers to recovery, and objective clinical evidence.
- Services that do not require the professional skills of a practitioner to perform or supervise are not medically necessary, even if they are performed or supervised by an acupuncture provider. Therefore, if the continuation of a patient's care can proceed safely and effectively through a home exercise program or self-management program, services are not indicated or medically necessary.
- The use of passive modalities in the treatment of subacute or chronic conditions beyond the acute inflammatory response phase requires documentation of the anticipated benefit and condition-specific rationale in order to be considered medically necessary.
- The treatment plan includes the use of therapeutic procedures to address functional deficits and ADL restrictions.
- The set therapeutic goals are functionally oriented, realistic, measurable, and evidence based.
- The proposed date of release/discharge from treatment is clearly defined.
- The selected treatment/therapies are appropriately correlated with the nature and severity of the patient's condition(s) and treatment goals.
- Functional Outcome Measures (FOM) demonstrate minimal clinically important difference (MCID) from baseline results through periodic reevaluations during the course of care. This is important in order to determine the need for continued care, the appropriate frequency of visits, estimated date of release from care, and if a change in the treatment plan or a referral to an appropriate health care practitioner/specialist is indicated.
- Home care, self-care, and active-care instructions are documented.

Assessment of Diagnostic Testing

- Laboratory tests are performed only when medically necessary to improve diagnostic accuracy and treatment planning. Abnormal values are professionally interpreted as they relate to the patient's complaint(s) or to unrelated co-morbid conditions that may or may not impact the patient's prognosis and proposed treatment.
- X-ray procedures are performed only when medically necessary to improve diagnostic accuracy and treatment planning. (Indicators from history and physical

examination indicating the need for x-ray procedures are described in the *X-Ray Guidelines (CPG 1 - S)* clinical practice guideline).

- Advanced imaging studies, when medically necessary and/or available, are used to evaluate for structural integrity and to rule out osseous, related soft tissue pathology, or other pathology.
- Imaging or special studies must be appropriate given the nature and severity of the patient's condition(s) and the findings obtained from those studies are likely to influence the basis for and character of the proposed treatment.

6.5 Factors that Influence Adverse Determinations of Clinical Services (Partial Approvals/Denials)

Factors that influence adverse determinations of clinical services may include but are not limited to these specific considerations and other guidelines and factors identified elsewhere in this policy. Topics/factors covered elsewhere in this guideline are also applicable in this section and may result in an adverse determination on medical necessity review. To avoid redundancy, many of those factors have not been listed below.

Additional Factors Considered in Determination of Medical Necessity

History / Complaints / Patient Reported Outcome Measures

- The patient's complaint(s) and/or symptom(s) are not clearly described.
- There is poor correlation and/or a significant discrepancy between the complaint(s) and/or symptom(s) as documented by the treating practitioner and as described by the patient.
- The patient's complaint(s) and/or symptom(s) have not demonstrated clinically significant improvement.
- The nature and severity of the patient's complaint(s) and/or symptom(s) are insufficient to substantiate the medical necessity of any/all submitted services.
- The patient has little, or no pain as measured on a valid pain scale.
- The patient has little or no functional deficits using a valid functional outcome measure or as otherwise documented by the practitioner.

Evaluation Findings

- There is poor correlation and/or a significant discrepancy in any of the following:
  - Patient's history
  - Subjective complaints
  - Objective findings
  - Diagnosis
  - Treatment plan

- The application of various exam findings to diagnostic or treatment decisions are not clearly described or measured. (e.g., severity, intensity, professional interpretation of results, significance).
- The patient's objective findings have not demonstrated clinically significant improvement.
- The objective findings are essentially normal or are insufficient to support the medical necessity of any/all submitted services.
- The submitted objective findings are insufficient due to any of, but not limited to, the following reasons:
    - Old or outdated relative to the requested dates of service
    - Do not properly describe the patient's current status
    - Do not substantiate the medical necessity of the current treatment plan
    - Do not support the patient's diagnosis/diagnoses
    - Do not correlate with the patient's subjective complaint(s) and/or symptom(s)
- Not all of the patient's presenting complaints were properly examined.
- The patient does not have any demonstrable functional deficits or impairments.
- The patient has not made reasonable progress toward pre-clinical status or functional outcomes under the initial treatment/services.
- Clinically significant therapeutic progress is not evident through a review of the submitted records. This may indicate that the patient has reached maximum therapeutic benefit.
- The patient is approaching or has reached maximum therapeutic benefit.
- The patient's exam findings have returned to pre-injury status or prior level of function.
- There is inaccurate reporting of clinical findings.
- The exam performed is for any of the following:
    - Wellness
    - Pre-employment
    - Sports pre-participation
- The exam performed is non-standard and solely technique/protocol based.

Assessment/Diagnosis

- The assessment/diagnosis is not supported by one or more of the following:
    - Patient's history (e.g., date/mechanism of onset)
    - Subjective complaints (e.g., nature and severity, location)
    - Objective findings (e.g., not clearly defined and/or quantified, not professionally interpreted, significance not noted)
    - Referral diagnosis when a referral is required

Submitted Medical Records

- The submitted records are insufficient to reliably verify pertinent clinical information, such as (but not limited to):
  - Patient's clinical health status
  - The nature and severity of the patient's complaint(s) and/or symptom(s)
  - Date/mechanism of onset
  - Objective findings
  - Diagnosis/diagnoses
  - Response to care
  - Functional deficits/limitations
- There are daily notes submitted for the same dates of service with different/altered findings without an explanation.
- There is evidence of duplicated or nearly duplicated records for the same patient for different dates of service, or for different patients.
- There is poor correlation and/or a significant discrepancy between the information presented in the submitted records with the information presented during a verbal communication between the reviewing CQE and treating practitioner.
- The treatment time (in minutes) and/or the number of units used in the performance of a timed service (e.g., modality, procedure) during each encounter/office visit was not documented.
- Some or all of the service(s) submitted for review are not documented as having been performed in the daily treatment notes.

Treatment / Treatment Planning

- The submitted records show that the nature and severity of the patient's complaint(s) and/or symptom(s) require a limited, short trial of care in order to monitor the patient's response to care and determine the efficacy of the current treatment plan. This may include, but not limited to, any of the following:
  - Significant trauma affecting function
  - Acute/sub-acute stage of condition
  - Moderate-to-severe or severe subjective and objective findings
  - Possible neurological involvement
  - Presence of co-morbidities that may significantly affect the treatment plan and/or the patient's response to care
- There is poor correlation of the treatment plan with the nature and severity of the patient's complaint(s) and/or symptom(s), such as (but not limited to):
  - Use of acute care protocols for chronic condition(s)
  - Prolonged reliance on passive care
  - Active care and reduction of passive care are not included in the treatment plan

    - Use of passive modalities in the treatment of sub-acute or chronic conditions beyond the acute, inflammatory response time frame
    - Use of passive modalities as stand-alone treatments (which is rarely therapeutic) or as the sole treatment approach to the patient's condition(s)
- There is evidence from the submitted records that the patient's treatment can proceed safely and effectively through a home exercise program or self-management program.
- The patient's function has improved, complaints and symptoms have decreased, and patient requires less treatment (e.g., lesser units of services per office visit, lesser frequency, shorter total duration to discharge).
- The patient's symptoms and/or exam findings are mild and the patient's treatment plan requires a lesser frequency (e.g., units of services, office visits per week) and/or total duration.
- Therapeutic goals have not been documented. Goals should be measurable and written in terms of function and include specific parameters.
- Therapeutic goals have not been reassessed in a timely manner to determine if the patient is making expected progress.
- Failure to make progress or respond to care as documented within subjective complaints, objective findings and/or functional outcome measures.
- The patient's condition(s) is/are not amenable to the proposed treatment plan.
- Additional significant improvement cannot be reasonably expected by continued treatment and treatment must be changed or discontinued.
- The patient has had ongoing care without any documented lasting therapeutic benefits.
- The condition requires an appropriate referral and/or coordination with other appropriate health care services.
- The patient is not adhering to the treatment plan that includes lifestyle changes to help reduce frequency and intensity of symptoms.
- The patient is not adhering to treatment plan that includes medically necessary frequency and intensity of services.
- The use of multiple passive modalities with the same or similar physiologic effects to the identical region is considered a duplication of services and not reasonable or medically necessary.
- Home care, self-care, and active-care instructions are not implemented or documented in the submitted records.
- Uncomplicated diagnoses do not require services beyond the initial treatment plan before discharging the patient to active home/self-care.
- As symptoms and clinical findings improve the frequency of services (e.g., visits per week/month) did not decrease.

- The submitted services do not or no longer require the professional skills of the treating practitioner.
- The treatment plan is for any of the following:
    - Maintenance therapy
    - Preventive care
    - Elective/convenience/wellness care
    - Back school
    - Group therapy (not one-on-one)
    - Vocational rehabilitation or return to work programs
    - Work hardening programs
    - Routine educational, training, conditioning, return to sport, or fitness.
    - Non-covered condition
- There is duplication of services with other healthcare practitioners/specialties.
- The treatment plan is not supported due to, but not limited to, any of the following reasons:
    - Technique-/protocol-based instead of individualized and evidence based
    - Generic and not individualized for the patient's specific needs
    - Does not correlate with the set therapeutic goals
    - Not supported in the clinical literature (e.g., proprietary, unproven)
    - Not considered evidence-based and/or professionally accepted
- The treatment plan includes services that are considered not evidence-based, not widely accepted, unproven and/or not reasonable or medically necessary, or inappropriate or unrelated to the patient's complaint(s) and/or diagnosis/diagnoses. (e.g., Low level laser therapy, select forms of EMS such as microcurrent) Also see the *Techniques and Procedures Not Widely Supported as Evidence-Based (CPG 133 – S*) clinical practice guideline for complete list).

Health and Safety

- There are signs, symptoms and/or other pertinent information presented through the patient's history, exam findings, and/or response to care that require urgent attention, further testing, and/or referral to and/or coordination with other healthcare practitioners/specialists.
- There is evidence of the presence of Yellow and/or Red Flags. (See section on Red and Yellow Flags above.)
- There are historical, subjective, and/or objective findings which present as contraindications for the plan of care.

6.6 Referral / Coordination of Services

When a potential health and safety issue is identified, the CQE must communicate with the provider of services as soon as possible by telephone and/or through standardized

communication methods to recommend returning the patient back to the referring health care practitioner or referring the patient to other appropriate health care practitioner/specialist with the measure of urgency as warranted by the history and clinical findings.

Clinical factors that may require referral or coordination of services include, but are not limited to:

- Symptoms worsening following treatment
- Deteriorating condition (e.g., orthopedic, or neurologic findings, function, etc.)
- Reoccurring exacerbations despite continued treatment
- No progress despite treatment
- Unexplained diagnostic findings (e.g., suspicion of fracture)
- Identification of Red Flags
- Identification of co-morbid conditions that do not appear to have been addressed previously that represent absolute contraindications to services
- Constitutional signs and symptoms indicative of systemic condition (e.g., unintended weight loss of greater than 4.5 kg/10 lbs. over 6-month period)
- Inability to provoke symptoms with standard exam
- Treatment needed outside of scope of practice

The Clinical Policy is reviewed and approved by the ASH Clinical Quality committees that are comprised of contracted network practitioners including practitioners of the same clinical discipline as the treating providers for whom compliance with the practices articulated in this document is required. Guidelines are updated at least annually, or as new information is identified that result in material changes to one or more of these policies.

7. DESCRIPTION AND BACKGROUND

The practice of traditional acupuncture is predicated upon several fundamental underlying principles. The existence of a series of meridians that course through the body along which are located discrete points that correspond to specific organs and/or have particular clinical significance; a vital energy, “chi,” flows through the meridians and the acupuncture points regulating bodily functions; it is the disruption of this flow of energy that therapeutic acupuncture is said to address.

Medical acupuncturists choose anatomically and physiologically important treatment points which may include both traditional acupuncture points and other non-traditional fixed points. "More attention is focused on the tissue level (e.g., muscle rather than skin) and the type and amount of stimulation given" (White, 2009). Western medical acupuncture has been an available treatment modality in the UK and other countries for many years.

Acupuncture typically utilizes unique diagnostic procedures to evaluate the meridian/chi system. This includes an evaluation of the patient's chief complaint and related health status through standardized diagnostic interviewing and examination techniques. Interviews are based on the traditional "Ten Questions" and examinations include, but are not limited to, evaluation of meridians, points, general vitality and behavior, the radial pulses and the tongue. Based upon the patient's complaint and the findings of these diagnostic procedures, individualized treatment regimens are developed that specify treatment variables such as the acupuncture points to be utilized, needle placement, and type of needle stimulation. There are several variations on the use of acupuncture needles for treatment, including acupuncture and dry needling. Individuals may feel different sensations during acupuncture treatments. The "De Qi" often thought of as the "arrival of qi" energy at the needle insertion site can be experienced in various ways such as numbness, tingling, electrical sensation, fullness, distension, soreness, warmth tenseness, pulling or itching. Acupuncturists may additionally facilitate this qi sensation by twirling, plucking or thrusting of acupuncture needles. There are also numerous variations of manually or electrically stimulated "needling" techniques, as well as multiple "non-needling" acupuncture techniques.

Depending upon the jurisdiction, those licensed to administer acupuncture may include licensed acupuncturists (LAc), medical/osteopathic physicians (MD/DO), chiropractors (DC), naturopaths (ND), oriental medicine doctors (OMD), podiatrists (DPM), dentists (DDS/DMD), nurse practitioners (NP), physician assistants (PA), as well as other designated health care providers. Depending upon the practitioner's training, different systems of acupuncture diagnosis and treatment may be used.

Multiple different biological mechanisms have been proposed and studied to explain acupuncture. The mechanism of action of analgesia secondary to acupuncture remains unclear, and likely multimodal. However, there are some physiologic effects that have been noted with its use. Many of these proposed mechanisms are centrally mediated and others are local physiologic responses. For example, it is thought that the immediate analgesic effects of acupuncture may be dependent on neural (nerve) innervation. Most commonly it is thought that the stimulation of the acupuncture needle triggers the release of endogenous opioids (endorphins) in various parts of the brain. This effect seems the most pronounced in electro-acupuncture. Another possible mechanism is through the diffuse noxious inhibitory control pathway (DNIC). According to DNIC, a noxious stimulus applied to any region of the body can induce immediate suppression of pain transmission in neurons of the trigeminal caudalis and/or the spinal dorsal horn. Another theory proposes that the descending serotoninergic inhibitory pathway is key to acupuncture analgesia. In addition, there is some preliminary evidence that acupuncture may have effects on the inflammatory response mediated through the autonomic nervous system. Local tissue effects including release of adenosine at the site of needle stimulation have also been observed as have

increases in local blood flow. Other modes of action have been reported including local and myofascial trigger point needling effects, segmental pain effects, extra-segmental pain effects, and central regulatory effects (White et al., 2008). Current available evidence indicates that insertion of acupuncture needles has an effect above waiting list controls but there is limited available evidence to define whether exact needle placement on established "Traditional" Acupuncture points is necessary to produce a result. Specific treatment parameters of acupoint selections, number of points needled, depth of insertion, responses elicited, needle stimulation- method and strength, needle retention time, needle types and the relevance of experience of the acupuncturist have not been adequately determined. Future trials are needed to establish the standardization of these characteristics as well as to compare the effectiveness of different acupuncture techniques.

None of the mechanisms of action postulated for acupuncture effects are sufficiently well understood to have established a dispositive answer to describe the exact physiological mechanism by which acupuncture produces its analgesic and antiemetic effects.

8. EVIDENCE AND RESEARCH

Evaluating the clinical efficacy of acupuncture in the context of clinical trials is challenging primarily because of the difficulty of designing randomized trials with appropriate blinding of both subjects and providers. Many studies lack appropriate controls, adequate study size, randomization and/or consistent outcome measures.

Study controls for comparing real acupuncture (also referred to as verum acupuncture) typically include a placebo, sham acupuncture, standard treatment, or no treatment. Sham acupuncture is the most often used control in studies evaluating the efficacy of acupuncture. However, there is no standardized method for employing sham acupuncture and no consensus on needle placement, making it difficult to generalize findings across studies. The goal of applying sham acupuncture is to refrain from stimulating acupuncture points. In many studies, sham is done at irrelevant acupuncture sites; however, evidence has shown sham acupuncture evokes physiological responses. Because the evidence suggests that sham acupuncture is not truly a physiologically neutral event, its use as a control in clinical trials is debatable. It is difficult to distinguish between the specific effects of treatment versus that of the placebo. It has been reported that the ratio of improvement in sham groups was substantially higher than in truly inert placebo groups (Madsen, et al., 2009; Ezzo, et al., 2000). Although initially believed to have no effect, some researchers contend that needle placement in any position invokes a biological response that may interfere with the interpretation of findings.

There are now several thousand RCTs evaluating the effectiveness of acupuncture for hundreds of different conditions. The literature is examined below.

8.1 Chronic Pain

There are several Cochrane Reviews of acupuncture for pain that are inconclusive due to the small number of studies and/or the low quality of studies. Conditions reviewed include menstrual pain (Smith et al., 2011), elbow pain (Green et al., 2002), cancer pain (Paley et al., 2011), rheumatoid arthritis (Casimiro et al., 2005) and acute ankle sprain (Kim et al., 2014).

In 2009 BMJ published a systematic review of acupuncture for pain that came to a largely negative conclusion (Madsen et al., 2009). The review focused on trials that included both sham acupuncture and no acupuncture controls. Thirteen trials with 3025 patients were identified. Conditions included OA of the knee, tension-type headaches, migraine headache, low back pain, fibromyalgia, abdominal scar pain, and postoperative pain. A small difference was found between acupuncture and placebo acupuncture, comparable to 4 mm on a 100 mm visual analog scale. A larger effect equal to 10 mm was found between placebo acupuncture and no acupuncture. This 10 mm difference is considered to be at the margin of clinical significance. They find that overall the analgesic effects of acupuncture are small and that methodological limitations of the trials make it impossible to determine whether any of these results can be attributed to specific treatment effects rather than placebo. They conclude, "Whether needling at acupuncture points, or at any site, reduces pain independently of the psychological impact of the treatment ritual is unclear."

Hopton and Macpherson (2010) conducted a systematic review of meta-analyses of acupuncture compared to placebo for acute and chronic pain. The review criteria yielded eight studies, two for low back pain, four on knee pain, and two for headaches. The review found that for osteoarthritis of the knee and headache, acupuncture was more effective than placebo both in the short term and in the long term. For low back pain short term treatment effects were greater than placebo, but for the longer term there was an inconclusive finding. The authors conclude that acupuncture has specific effects beyond placebo for a wide range of pain syndromes. They further note that this conclusion is now broadly reflected in the scientific literature and that more salient research should shift focus from placebo-related questions to more practical questions about whether the overall benefit is clinically meaningful and cost-effective.

Vickers et al. conducted a meta-analysis of trials of acupuncture for chronic pain (Vickers et al., 2012). Eligible trials included those for mechanical low back and neck pain, shoulder pain, headache and osteoarthritis. Study subjects were required to have had pain for a minimum of four weeks and be followed for at least four weeks after the end of treatment. There were no restrictions on what outcomes measures could be used. The analysis identified 29 trials that met these criteria with a total of 17,922 individual patients analyzed. The analysis found acupuncture to be superior to both sham and no acupuncture control for each of the four conditions studied (all $p<0.001$). The effect sizes were similar across all

pain conditions. Patients receiving acupuncture had less pain, with scores 0.23 and 0.15 standard deviations lower than sham controls for back and neck pain, osteoarthritis, and chronic headache respectively; the effect sizes in comparison to no acupuncture controls were 0.55, 0.57 and 0.42. It is worth noting that the differences between acupuncture and sham are quite modest when compared to the differences between acupuncture and no acupuncture. Sensitivity analyses including for publication bias did not change these findings. The authors concluded, "Our results from individual patient data meta-analyses of nearly 18,000 randomized patients on high quality trials provide the most robust evidence to date that acupuncture is a reasonable referral option for patients with chronic pain."

A 2013 Cochrane Review examined acupuncture for the treatment of fibromyalgia (Deare et al., 2013). Nine trials with 395 subjects were included. These included both needle acupuncture and electro-acupuncture therapies. The overall conclusion was that there was low to moderate quality evidence that acupuncture improves pain and stiffness in people with fibromyalgia. Sham acupuncture had similar effects. The effects of electro-acupuncture are somewhat greater than needle acupuncture and both are considered safe. These findings are qualified due to the low number and quality of studies.

MacPherson et al. (2017) aimed to determine the trajectory of pain scores over time after acupuncture, using a large individual patient data set from high-quality randomized trials of acupuncture for chronic pain. The available individual patient data set included 29 trials and 17,922 patients. The chronic pain conditions included musculoskeletal pain (low back, neck, and shoulder), osteoarthritis of the knee, and headache/migraine. Authors used meta-analytic techniques to determine the trajectory of posttreatment pain scores. Data on longer term follow-up were available for 20 trials, including 6376 patients. The central estimate suggests that approximately 90% of the benefit of acupuncture relative to controls would be sustained at 12 months. Authors suggest that the effects of a course of acupuncture treatment for patients with chronic pain do not seem to decrease importantly over 12 months.

AHRQ published a systematic review by Skelly et al. (2018) on Noninvasive Nonpharmacological Treatment for Chronic Pain. Acupuncture that improved function and/or pain for at least 1 month was found for chronic low back, chronic neck pain, and fibromyalgia. Skelly et al. (2020) updated the evidence from their 2018 report assessing persistent improvement in outcomes following completion of therapy for noninvasive nonpharmacological treatment for selected chronic pain conditions. For chronic low back pain, function improved over short and/or intermediate term for acupuncture (SOE low). Improvements in pain at short term were seen for acupuncture (SOE: moderate). For

chronic neck pain, acupuncture improved function short and intermediate term, but there was no pain improvement compared with sham acupuncture (SOE: low). Functional improvements for fibromyalgia were seen with acupuncture (SOE: moderate) short term compared with usual care, attention control, or sham treatment. At intermediate term, there was functional improvement with acupuncture (SOE: moderate).

National Institute for Health and Care Excellence (NICE) guideline (2021) examined the literature on acupuncture and chronic pain. Findings included the following:

- Acupuncture versus sham acupuncture
  - Pain reduction
    - Very low quality evidence from 13 studies with 1230 participants showed a clinically important benefit of acupuncture compared to sham acupuncture at ≤3 months.
    - Low quality evidence from 2 studies with 159 participants showed a clinically important benefit of acupuncture compared to sham acupuncture at ≤3 months.
    - Low quality evidence from 4 studies with 376 participants showed no clinically important difference between acupuncture and sham acupuncture at >3 months.
    - Moderate quality evidence from 2 studies with 159 participants showed a clinically important benefit of acupuncture compared to sham acupuncture at >3 months.
    - Low quality evidence from 1 study with 61 participants showed no clinically important difference between acupuncture and sham acupuncture at >3 months
  - Quality of life
    - Low to moderate quality evidence from 2 studies with 210 participants showed a clinically important benefit of acupuncture compared to sham acupuncture at ≤3 months.
    - Moderate quality evidence from 1 study with 158 participants showed sham acupuncture to have a clinically important improvement compared to acupuncture at ≤3 months.
    - Very low quality evidence from 3 studies with 244 participants showed no clinically important difference between acupuncture and sham acupuncture at ≤3 months.
    - Very low quality evidence from 2 studies with 168 participants showed a clinically important benefit of acupuncture compared to sham acupuncture at ≤3 months.
    - Very low to low quality evidence from 1 study with 178 participants showed a clinically important benefit, clinically important harm and no clinically

important difference of acupuncture compared to sham acupuncture at ≤3 months (various quality of life subscales).
    - Moderate quality evidence from 2 studies with 159 participants showed a clinically important benefit of acupuncture compared to sham acupuncture at ≤3 months.
    - Low quality evidence from 1 study with 72 participants showed a clinically important benefit of acupuncture compared to sham acupuncture at ≤3 months.
    - Very low quality evidence from 1 study with 76 participants showed a clinically important benefit of sham acupuncture compared to verum acupuncture at >3 months.
    - Low quality evidence from 1 study with 96 participants showed no clinically important difference between acupuncture and sham acupuncture at >3 months.
    - Low quality evidence from 1 study with 153 participants showed a clinically important benefit of acupuncture compared to sham acupuncture at >3 months.
    - Moderate quality evidence from 1 study with 159 participants showed a clinically important benefit of acupuncture compared to sham acupuncture at >3 months.
  - Physical function
    - Very low quality evidence from 1 study with 118 participants showed no clinically important difference between acupuncture and sham acupuncture at ≤3 months.
    - Very low quality evidence from 1 study with 106 participants showed no clinically important difference between acupuncture and sham acupuncture at >3 months.
- Acupuncture versus usual care
  - Pain reduction
    - Low quality evidence from 5 studies with 234 participants showed a clinically important benefit of acupuncture compared to usual care at ≤3 months. Low quality evidence from 2 studies with 384 participants showed no clinically important difference between acupuncture and usual care at ≤3 months.
    - Moderate quality evidence from 1 study with 3162 participants showed a clinically important benefit of acupuncture compared to usual care at ≤3 months.
    - Moderate quality evidence from 1 study with 344 participants showed no clinically important difference between acupuncture and usual care at >3 months.

- Quality of life
  - Moderate quality evidence from 1 study with 3213 participants showed a clinically important benefit of acupuncture compared to usual care at ≤3 months. Very low quality evidence from 1 study with 100 participants showed both a clinically important benefit and no clinically important difference between acupuncture and usual care at ≤3 months (various quality of life subscales).
  - Low quality evidence from 1 study with 204 participants showed a clinically important benefit of acupuncture compared to usual care at >3 months.
- Physical function
  - Very low quality evidence from 1 study with 45 participants showed no clinically important difference between acupuncture and usual care at ≤3 months.
  - Very low quality evidence from 1 study with 100 participants showed a clinically important benefit of acupuncture compared to usual care at ≤3 months.
- Pain self-efficacy
  - Very low quality evidence from 1 study with 294 participants showed a clinically important benefit of acupuncture compared to usual care at ≤3 months.
- Pain interference
  - Very low-quality evidence from 1 study with 100 participants showed a clinically important benefit of acupuncture compared to usual care at >3 months.

8.2 Osteoarthritis

A Cochrane Review of acupuncture for peripheral joint arthritis identified sixteen trials (3498 individual patients) of adequate quality for review (Manheimer et al., 2010). Twelve of these trials included only people with OA of the knee, three were for OA of the hip and one trial included both hip and knee. Acupuncture showed statistically significant, short term improvements in OA pain and function. However, these differences were not considered to be clinically significant. Using only studies with sham controls deemed adequate to blind participants, these differences were small and not statistically significant. On a pain scale of 0-20, these differences were in the range of 3-4 points. On a functional scale of 0-68, improvements ranged from 3 to 11 points. However, greater effects were seen when compared to waiting list controls. The overall conclusion was that at both 8 and 26 week end points, acupuncture offered small benefits in pain and function. These benefits were deemed to be at least partially due to non-specific treatment effects. Atalay et al. (2021) sought to determine the effect of acupuncture treatment and physiotherapy on pain, physical function, and quality of life (QOL) in patients with knee osteoarthritis (KOA). One hundred patients with KOA were randomly divided into the acupuncture group and

the physiotherapy group. Both treatments were given in 12 sessions over 6 weeks. Thirteen acupuncture points were selected for the knee. Local points were GB34, SP10, SP9, ST36, ST35, ST34, EX-LE2, EX-LE5, EXLE4, and distal (distant) points were defined as KI3, SP6, LI4, and ST41. The Visual Analog Scale (VAS) was used to measure pain intensity. The Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC) and the 36-Item Short Form Health Survey (SF-36) were used to determine functional status and health-related QOL, respectively. All patients were evaluated at baseline, after the last treatment, and at the 12-week follow-up period. There was no statistically significant difference between the acupuncture group and physiotherapy group in terms of pain, total WOMAC, and SF-36 levels at baseline, after treatment, and at the 12th week after treatment ($P > 0.05$). Both treatments significantly improved functional status and decreased the level of pain assessed by VAS at the 12-week follow-up of the study. There was no adverse advent related to therapeutic methods. Authors concluded that the acupuncture and physiotherapy performed twice weekly for 6 weeks have similar effects with regard to pain, functional status, and QOL. There were no significant differences between the acupuncture and physiotherapy groups in relief of pain, improved functional status, and QOL in the treatment of KOA. Both acupuncture and physiotherapy treatments were found to yield significantly superior results when compared with baseline values.

8.3 Headache

Linde et al. conducted a Cochrane Review of acupuncture for tension-type headaches (Linde et al., 2009). Eleven trials with 2317 subjects met the inclusion criteria. Two of the trials compared acupuncture to routine care (including self-care) and found clinically and statistically significant benefits to acupuncture for both headache frequency and pain intensity. In these two trials 47% of patients receiving acupuncture reported a decrease in the number of headache days by at least 50%, compared to 16% of patients in the control groups. Six of the trials compared acupuncture to some form of sham acupuncture where needle placement was not guided by any specific acupuncture findings. In this comparison, 50% of the "true" acupuncture patients experienced a greater than 50% reduction in headache pain compared to 41% in the sham controls. Three trials compared acupuncture to massage, physiotherapy, or relaxation. The methodological quality of these studies was poor and the results difficult to interpret, but overall there appeared to be a slight benefit to acupuncture compared to these interventions. A previous Cochrane review of this topic yielded inconclusive results. However, the addition of six newer trials in this review led the authors to conclude that acupuncture could be "a valuable non-pharmacological tool in patients with frequent episodic or chronic tension-type headaches."

Another Cochrane Review examined acupuncture for migraine headache prophylaxis (Linde et al., 2009). Twenty-two trials with 4419 participants met the inclusion criteria. Six of the trials compared acupuncture to no treatment or routine care. The acupuncture care resulted in fewer headaches than in the controls over 3-4 months. One of the trials

followed patients for nine months and the treatment effects were undiminished. Fourteen trials compared acupuncture to some form of sham intervention. The results of single trials varied considerably, but the pooled results did not show any clinically or statistically significant benefit to the "true" acupuncture. Four trials compared acupuncture to drug prophylaxis and demonstrated slightly better outcomes and fewer side effects in the acupuncture groups. Overall, the authors conclude that acupuncture should be considered a valid treatment option for migraine prophylaxis.

Turkistani et al. (2021) evaluated the effectiveness of acupuncture and manual therapy in tension-type headaches. Eight articles involving 3846 participants showed evidence that acupuncture and manual therapy can be valuable non-pharmacological treatment options for tension-type headaches. Acupuncture was compared to routine care or sham intervention. Acupuncture was not found to be superior to physiotherapy, exercise, and massage therapy. Randomized controlled trials done in various countries showed manual therapy also significantly decreased headache intensity. Manual therapy has an efficacy that equals prophylactic medication and tricyclic antidepressants in treating tension-type headaches. The available data suggests that both acupuncture and manual therapy have beneficial effects on treating symptoms of tension-type headache. However, further clinical trials looking at long-term benefits and risks are needed.

8.4 Low Back and Neck Pain

The Cochrane Review of acupuncture for low back pain (Furlan et al., 2005) has not been updated and is considered obsolete at this point. A systematic review and meta-analysis of acupuncture for non-specific low back pain by Lam et al. was published in Spine (Lam et al., 2013). They identified 32 relevant studies, 25 of which had usable data for a meta-analysis. They found clinically significant benefits to acupuncture when compared to sham acupuncture and no treatment in both pain and function. They also compared acupuncture to other common treatment modalities including NSAIDS, muscle relaxants and analgesics and found acupuncture to offer comparable relief. However, these findings were qualified because of the low overall quality of the studies.

The Cochrane Review for neck pain (Trinh et al., 2006) found 10 clinical trials that met inclusion criteria. All of these trials were for chronic neck pain. The overall quality of these trials was judged to be poor. They found that for short term follow-up, acupuncture was more effective than inactive controls. And they found limited evidence that acupuncture was more effective than massage therapy. Also, for neck pain with radiculopathy there was moderate evidence that acupuncture was more effective than waiting list control.

Under the aegis of the Agency for Healthcare Research and Quality (AHRQ), Furlan et al. evaluated the entire range of complementary and alternative therapies, including acupuncture, for back and neck pain (Furlan et al., 2010). For acupuncture, a total of 105

clinical trials were evaluated. Acupuncture was found to be superior to placebo for chronic nonspecific low back pain, but only immediately post-treatment. But acupuncture was not different from placebo in post-treatment disability, pain medication intake, or global improvement in chronic nonspecific low back pain. Acupuncture and sham acupuncture were similar in reducing chronic non-specific neck pain immediately after treatment. Both were superior to no treatment in improving pain intensity, disability, well-being (SF-36), and range of motion immediately after the treatment. In general, trials that applied sham-acupuncture tended to produce negative results (i.e., statistically non-significant) compared to trials that applied other types of placebo (e.g., TENS, medication, laser). This can be interpreted as sham acupuncture having greater treatment effects than the other comparators.

Cho et al. evaluated the effects of acupuncture for chronic low back pain (Cho et al., 2013). One hundred thirty adults aged 18 to 65 years with chronic, nonspecific low back pain (cLBP) of at least three months duration were randomized to either individualized, traditional acupuncture, or to a sham needling procedure. The sham consisted of using non-penetrating, semi-blunt needles at non-acupuncture points. The primary outcome measure was a visual analog scale (VAS) for bothersomeness, and the secondary outcome measure was function (Oswestry). Patients were treated twice weekly for six weeks. VAS for "bothersomeness" scores for the real acupuncture groups decreased by 3.36 points, compared with 2.27 points for participants receiving sham acupuncture at the primary end point. There were no significant differences in disability scores and other secondary outcomes measures between the two treatment groups.

Yuan et al. (2015) reviewed and analyzed the existing data about pain and disability in TCM treatments for NP and LBP. Seventy-five randomized controlled trials (n = 11077) were included. Almost all of the studies investigated individuals experiencing chronic NP (CNP) or chronic LBP (CLBP). Authors concluded that acupuncture, acupressure, and cupping could be efficacious in treating the pain and disability associated with CNP or CLBP in the immediate term. Zeng and Chung (2015) aimed to summarize and evaluate the available systematic reviews on the clinical effectiveness and cost-effectiveness of acupuncture for the management of chronic nonspecific low back pain (cnLBP), and to identify the safety of acupuncture for the management of cnLBP. Seventeen systematic reviews were included. Five found that acupuncture was more effective when compared with a no treatment/waiting list control, as there were eight systematic reviews and meta-analysis providing positive and consistent findings. Seven systematic reviews providing positive findings of the comparison of acupuncture to sham acupuncture/passive modality treatment. Three systematic reviews of multiple RCTs also indicated positive and consistent findings of the comparison of acupuncture plus an intervention vs an intervention alone. Overall, findings on the effectiveness of acupuncture for cnLBP were consistent.

Liu et al. examined the set of systematic reviews of acupuncture for low back pain (Liu et al., 2015). They identified 16 systematic reviews, the overall quality of which they judged to be low. They found inconclusive evidence of a benefit for acupuncture compared to a sham for acute low back pain. For chronic low back pain there was consistent evidence of a benefit for short term pain relief and functional improvement when compared to sham or to no treatment. This benefit was found both when acupuncture was used in isolation and when used as an adjunct treatment.

Zeng and Chung (2015) aimed to summarize and evaluate the available systematic reviews on the clinical effectiveness and cost-effectiveness of acupuncture for the management of chronic nonspecific low back pain (cnLBP), and to identify the safety of acupuncture for the management of cnLBP. Seventeen systematic reviews were included. Five found that acupuncture was more effective when compared with a no treatment/waiting list control, as there were eight systematic reviews and meta-analysis providing positive and consistent findings. Seven systematic reviews providing positive findings of the comparison of acupuncture to sham acupuncture/passive modality treatment. Three systematic reviews of multiple RCTs also indicated positive and consistent findings of the comparison of acupuncture plus an intervention vs an intervention alone. Overall, findings on the effectiveness of acupuncture for cnLBP were consistent.

In another AHRQ publication by Chou et al. (2016) titled Noninvasive Treatments for Low Back Pain, noted the following key points:

- For acute low back pain, a systematic review found acupuncture associated with lower pain intensity versus sham acupuncture using nonpenetrating needles; three other trials reported effects consistent with these findings. One trial of sham acupuncture using penetrating needles to nonacupuncture points found no effect on pain. These were no clear effects on function in 5 trials (Strength of Evidence (SOE): low for pain and function).
- For chronic low back pain, a systematic review found acupuncture associated with lower pain intensity versus sham acupuncture (superficial needling at acupuncture or nonacupuncture points, or nonpenetrating pressure at acupuncture points) immediately at the end of treatment and at up to 12 weeks, but there were no differences in function. Four additional trials reported results consistent with these findings (SOE: moderate for pain and function).
- For chronic low back pain, a systematic review found acupuncture associated with lower pain intensity and better function immediately after treatment versus no acupuncture. Mean effects on pain ranged from 7 to 24 points on a 0- to 100-point scale; for function one trial reported a difference of 8 points on a 0- to 100-point scale and the other two trials; two trials showed small or no clear differences at longer-term follow up (SOE: moderate for pain and function).

- For acute low back pain, a systematic review found acupuncture associated with slightly greater likelihood of overall improvement versus NSAIDs at the end of treatment (SOE: low).
- For chronic low back pain, a systematic review found acupuncture associated with better pain relief and improvement in function immediately postintervention (SOE: low).
- Harms of acupuncture were poorly reported in the trials, though no serious adverse events were reported (SOE: low).

Qaseem et al. (2017) provided clinical recommendations on noninvasive treatment of low back pain: Recommendation 1: Given that most patients with acute or subacute low back pain improve over time regardless of treatment, clinicians and patients should select nonpharmacologic treatment with superficial heat (moderate-quality evidence), massage, acupuncture, or spinal manipulation (low-quality evidence). (Grade: strong recommendation). Recommendation 2: For patients with chronic low back pain, clinicians and patients should initially select nonpharmacologic treatment with exercise, multidisciplinary rehabilitation, acupuncture, mindfulness-based stress reduction (moderate-quality evidence), tai chi, yoga, motor control exercise, progressive relaxation, electromyography biofeedback, low-level laser therapy, operant therapy, cognitive behavioral therapy, or spinal manipulation (low-quality evidence). (Grade: strong recommendation).

Chou et al. (2017) updated the 2007 American College of Physicians guideline that addressed nonpharmacologic treatment options for low back pain. New evidence was available. Authors systematically reviewed the current evidence on nonpharmacologic therapies for acute or chronic non radicular or radicular low back pain. Randomized trials of 9 nonpharmacologic options versus sham treatment, wait list, or usual care, or of 1 nonpharmacologic option versus another were included. New evidence indicated that tai chi (strength of evidence [SOE], low) and mindfulness-based stress reduction (SOE, moderate) are effective for chronic low back pain and strengthens previous findings regarding the effectiveness of yoga (SOE, moderate). Evidence continues to support the effectiveness of exercise, psychological therapies, multidisciplinary rehabilitation, spinal manipulation, massage, and acupuncture for chronic low back pain (SOE, low to moderate). Limited evidence shows that acupuncture is modestly effective for acute low back pain (SOE, low). The magnitude of pain benefits was small to moderate and generally short term; effects on function generally were smaller than effects on pain.

Wong et al. (2017) authored a systematic review for the Ontario Protocol for Traffic Injury Management (OPTIMa) Collaboration. According to high-quality guidelines: (1) all patients with acute or chronic LBP should receive education, reassurance and instruction on self-management options; (2) patients with acute LBP should be encouraged to return

to activity and may benefit from paracetamol, nonsteroidal anti-inflammatory drugs (NSAIDs), or spinal manipulation; (3) the management of chronic LBP may include exercise, paracetamol or NSAIDs, manual therapy, acupuncture, and multimodal rehabilitation (combined physical and psychological treatment); and (4) patients with lumbar disc herniation with radiculopathy may benefit from spinal manipulation. According to Tice et al. (2017), the strength of evidence appears adequate to support coverage of acupuncture, CBT, MBSR, and yoga for chronic low back pain. Evidence-based boundaries on duration of therapy and on repetitive courses of therapy are reasonable given the potential for inappropriate overuse of services. Authors reported that there was no evidence on the concurrent use of multiple modalities, so concurrent treatment should be treated on a case-by-case basis.

Xiang et al. (2017) sought to establish whether sham acupuncture (SA) or placebo acupuncture (PA) was more efficacious for reducing low back pain (LBP) than other routine treatments and to discuss whether SA or PA is appropriate for randomized controlled trials of acupuncture for LBP. Review identified 7 trials (1768 participants); all were included in the meta-analysis. They found statistically significant differences in pain reduction post-intervention between SA or PA and routine care or a waiting list, however, no significant difference was observed between SA or PA and routine care or no treatment for post-intervention function. Authors concluded that compared with routine care or a waiting list, SA or PA was more efficacious for pain relief post-intervention. Concluding that SA or PA is appropriate for acupuncture research would be premature. Guidelines evaluating SA or PA control methods are needed to determine the specific effect of acupuncture over placebo.

Mu et al. (2020) authored an updated Cochrane review. This review is a split from an earlier Cochrane review and it focuses on chronic LBP. Mu et al. (2020) assessed the effects of acupuncture compared to sham intervention, no treatment, or usual care for chronic nonspecific LBP. Authors included only randomized controlled trials (RCTs) of acupuncture for chronic nonspecific LBP in adults. They excluded RCTs that investigated LBP with a specific etiology. Trials comparing acupuncture with sham intervention, no treatment, and usual care were included. The primary outcomes were pain, back-specific functional status, and quality of life; the secondary outcomes were pain-related disability, global assessment, or adverse events. Authors included 33 studies (37 articles) with 8270 participants. The majority of studies were carried out in Europe, Asia, North and South America. Seven studies (5572 participants) conducted in Germany accounted for 67% of the participants. Sixteen trials compared acupuncture with sham intervention, usual care, or no treatment. Most studies had high risk of performance bias due to lack of blinding of the acupuncturist. A few studies were found to have high risk of detection, attrition, reporting or selection bias. Mu et al. (2020) found low-certainty evidence (seven trials, 1403 participants) that acupuncture may relieve pain in the immediate term (up to seven

days) compared to sham intervention, visual analogue scale (VAS) 0-100). The difference did not meet the clinically important threshold of 15 points or 30% relative change. Very low-certainty evidence from five trials (1481 participants) showed that acupuncture was not more effective than sham in improving back-specific function in the immediate term; corresponding to the Hannover Function Ability Questionnaire (HFAQ, 0 to 100, higher values better) change. Three trials (1068 participants) yielded low-certainty evidence that acupuncture seemed not to be more effective clinically in the short term for quality of life; corresponding to the physical 12-item Short Form Health Survey (SF-12, 0-100, higher values better) change. The reasons for downgrading the certainty of the evidence to either low to very low were risk of bias, inconsistency, and imprecision. We found moderate-certainty evidence that acupuncture produced greater and clinically important pain relief; (VAS, 0 to 100), and improved back function; five trials, 2960 participants; corresponding to the HFAQ change in the immediate term compared to no treatment. The evidence was downgraded to moderate certainty due to risk of bias. No studies reported on quality of life in the short term or adverse events. Low-certainty evidence (five trials, 1054 participants) suggested that acupuncture may reduce pain; not clinically important on 0 to 100 VAS) and improve back-specific function immediately after treatment; five trials, 1381 participants; corresponding to the HFAQ change compared to usual care. Moderate-certainty evidence from one trial (731 participants) found that acupuncture was more effective in improving physical quality of life but not mental quality of life in the short term. The certainty of evidence was downgraded to moderate to low because of risk of bias, inconsistency, and imprecision. Low-certainty evidence suggested a similar incidence of adverse events immediately after treatment in the acupuncture and sham intervention groups (four trials, 465 participants), and the acupuncture and usual care groups (one trial, 74 participants). The certainty of the evidence was downgraded due to risk of bias and imprecision. No trial reported adverse events for acupuncture when compared to no treatment. The most commonly reported adverse events in the acupuncture groups were insertion point pain, bruising, hematoma, bleeding, worsening of LBP, and pain other than LBP (pain in leg and shoulder). Authors concluded that acupuncture may not play a more clinically meaningful role than sham in relieving pain immediately after treatment or in improving quality of life in the short term, and acupuncture possibly did not improve back function compared to sham in the immediate term. However, acupuncture was more effective than no treatment in improving pain and function in the immediate term. Trials with usual care as the control showed acupuncture may not reduce pain clinically, but the therapy may improve function immediately after sessions as well as physical but not mental quality of life in the short term. The evidence was downgraded to moderate to very low certainty considering most of studies had high risk of bias, inconsistency, and small sample size introducing imprecision. The decision to use acupuncture to treat chronic low back pain might depend on the availability, cost and patient's preferences.

Su et al. (2021) critically evaluated the evidence for acupuncture as an effective treatment

for acute LBP (ALBP). Of the 13 eligible RCTs identified, 11 RCTs (involving 707 patients) provided moderate-quality evidence that acupuncture has a statistically significant association with improvements in VAS (visual analog scale) score. Two studies indicated that acupuncture did not influence the RMDQ (Roland-Morris Disability Questionnaire) scores more than the control treatment. Three studies suggested that acupuncture influenced the ODI (Oswestry Disability Index) scores more than the control treatment. Two studies suggested that acupuncture influenced the number of medications taken more than the control treatment. Authors conclude that acupuncture treatment of acute LBP was associated with modest improvements in the VAS score, ODI score, and the number of pills, but not the RMDQ score. However, findings should be considered with caution due to the low power original studies. High-quality trials are needed to assess further the role of acupuncture in the treatment of acute LBP.

Wu et al. (2021) evaluated and compared the efficacy and safety of different acupuncture therapies for ALBP. In total, nineteen randomized controlled trials (RCTs) comprising 1,427 participants were included. Results showed the following: (I) compared with placebo, motion style acupuncture (MSA), manual acupuncture (MA), and electroacupuncture (EA) were found to be more effective for decreasing VAS score; (II) compared with pharmacotherapy, MSA and MA were found to be more effective in reducing ROM score. Results of the surface under the cumulative ranking curve indicated that all acupuncture types were superior to placebo or pharmacotherapy in lowering VAS and ROM score. It was noted that MSA was the most effective treatment. Authors concluded that this study indicated that acupuncture therapy achieved good therapeutic effects in the treatment of ALBP, especially MSA therapy. Nevertheless, due to the low quality of the included trials, the credibility of conclusions is low. Further well-designed RCTs with high quality and large samples are still needed to evaluate the efficacy and safety of acupuncture therapy for ALBP.

Huang et al. (2021) investigated the effect and safety of acupuncture for the treatment of chronic spinal pain. Data was extracted from 22 RCTs including 2588 patients. Pooled analysis revealed that acupuncture can reduce chronic spinal pain compared to sham acupuncture), mediation control, usual care control, and no treatment control. In terms of functional disability, acupuncture can improve physical function at immediate-term follow-up, short-term follow-up, and long-term follow-up. In summary, compared to no treatment, sham acupuncture, or conventional therapy such as medication, massage, and physical exercise, acupuncture has a significantly superior effect on the reduction in chronic spinal pain and function improvement. Acupuncture might be an effective treatment for patients with chronic spinal pain and it is a safe therapy.

8.5 Cancer Pain

A Cochrane Review by Paley et al. reviewed the trials of acupuncture for cancer pain in

adults (Paley et al., 2011). Three RCTs with 204 patients met the inclusion criteria. One study compared traditional auricular acupuncture with auricular acupuncture at non-acupuncture points and with a control using non-invasive "ear seeds," at non-acupuncture points. The remaining two studies compared acupuncture with pain medication. The reviewers concluded that while there was some evidence of acupuncture effectiveness there was a high risk of bias in all studies and no conclusions could be reached regarding acupuncture effectiveness. Paley et al. (2015) updated the Cochrane review. They found five studies (with a total of 285 participants) that compared acupuncture against either sham acupuncture or pain-killing medicines. All five identified studies had small sample sizes, which reduces the quality of their evidence. Authors reported that none of the studies described in this review were big enough to produce reliable results. None of the studies reported any harm to the participants. They concluded that there was insufficient evidence to judge whether acupuncture is elective in relieving cancer pain in adults and that larger, well-designed studies are needed to provide evidence in this area.

Yang et al. (2021) analyzed currently available publications regarding the use of acupuncture for pain management among patients with cancer in palliative care settings. Five studies (*n*=189) were included in this systematic review. Results indicated a favorable effect of acupuncture on pain relief in palliative care for patients with cancer. Authors concluded that acupuncture may be an effective and safe treatment associated with pain reduction in the palliative care of patients with cancer. Further high-quality, adequately powered studies are needed in the future.

Ge et al. (2022) developed an evidence-based clinical practice guideline of acupuncture in the treatment of patients with moderate and severe cancer pain. Recommendations were developed through a Delphi consensus of an international multidisciplinary panel including 13 western medicine oncologists, Chinese medicine/acupuncture clinical practitioners, and two patient representatives. The certainty of evidence, patient preferences and values, resources, and other factors were fully considered in formulating the recommendations. The Grading of Recommendations Assessment, Development, and Evaluation (GRADE) approach was employed to rate the certainty of evidence and the strength of recommendations. The guideline proposed three recommendations: (1) a strong recommendation for the treatment of acupuncture rather than no treatment to relieve pain in patients with moderate to severe cancer pain; (2) a weak recommendation for the combination treatments with acupuncture/acupressure to reduce pain intensity, decrease the opioid dose, and alleviate opioid-related side effects in moderate to severe cancer pain patients who are using analgesics; and (3) a strong recommendation for acupuncture in breast cancer patients to relieve their aromatase inhibitor-induced arthralgia. This proposed guideline provides recommendations for the management of patients with cancer pain. The small sample sizes of evidence limit the strength of the recommendations and highlights the need for additional research.

Li et al. (2021) evaluated the effect of acupuncture on treatment-related symptoms among breast cancer survivors. The primary outcomes were pain, hot flashes, sleep disturbance, fatigue, depression, lymphedema, and neuropathy as individual symptoms. They also evaluated adverse events reported in acupuncture studies. Of 26 selected trials (2055 patients), 20 (1709 patients) were included in the meta-analysis. Acupuncture was more effective than control groups in improving pain intensity, fatigue, and hot flash severity. The subgroup analysis indicated that acupuncture showed trends but not significant effects on all the treatment-related symptoms compared with the sham acupuncture groups. Compared with waitlist control and usual care groups, the acupuncture groups showed significant reductions in pain intensity, fatigue, depression, hot flash severity, and neuropathy. No serious adverse events were reported related to acupuncture intervention. Mild adverse events (i.e., bruising, pain, swelling, skin infection, hematoma, headache, menstrual bleeding) were reported in 11 studies. This systematic review and meta-analysis suggest that acupuncture significantly reduces multiple treatment-related symptoms compared with the usual care or waitlist control group among breast cancer survivors. The safety of acupuncture was inadequately reported in the included studies. Based on the available data, acupuncture seems to be generally a safe treatment with some mild adverse events. These findings provide evidence-based recommendations for incorporating acupuncture into clinical breast cancer symptom management. Due to the high risk of bias and blinding issues in some RCTs, more rigorous trials are needed to confirm the efficacy of acupuncture in reducing multiple treatment-related symptoms among breast cancer survivors.

Zhang et al. (2021) evaluated the effects of acupuncture in women with breast cancer (BC), focusing on patient-reported outcomes (PROs). Out of the 2, 524 identified studies, 29 studies representing 33 articles were included in this meta-analysis. At the end of treatment (EOT), the acupuncture patients' quality of life (QoL) was measured by the QLQ-C30 QoL subscale, the Functional Assessment of Cancer Therapy-Endocrine Symptoms (FACT-ES), the Functional Assessment of Cancer Therapy-General/Breast (FACT-G/B), and the Menopause-Specific Quality of Life Questionnaire (MENQOL), which depicted a significant improvement. The use of acupuncture in BC patients lead to a considerable reduction in the scores of all subscales of the Brief Pain Inventory-Short Form (BPI-SF) and Visual Analog Scale (VAS) measuring pain. Moreover, patients treated with acupuncture were more likely to experience improvements in hot flashes scores, fatigue, sleep disturbance, and anxiety compared to those in the control group, while the improvements in depression were comparable across both groups. Long-term follow-up results were similar to the EOT results. Authors concluded that current evidence suggests that acupuncture might improve BC treatment-related symptoms measured with PROs including QoL, pain, fatigue, hot flashes, sleep disturbance and anxiety. However, a number of included studies report limited amounts of certain subgroup settings, thus more rigorous, well-designed and larger RCTs are needed to confirm our results.

8.6 Neuropathic Pain

Ju et al. (2017) assessed the analgesic efficacy and adverse events of acupuncture treatments for chronic neuropathic pain in adults. Randomized controlled trials (RCTs) with treatment duration of eight weeks or longer comparing acupuncture (either given alone or in combination with other therapies) with sham acupuncture, other active therapies, or treatment as usual, for neuropathic pain in adults were included in this review. The primary outcomes were pain intensity and pain relief. The secondary outcomes were any pain-related outcome indicating some improvement, withdrawals, participants experiencing any adverse event, serious adverse events and quality of life. Authors included six studies involving 462 participants with chronic peripheral neuropathic pain (442 completers (251 male), mean ages 52 to 63 years). Most studies included a small sample size (fewer than 50 participants per treatment arm) and all studies were at high risk of bias for blinding of participants and personnel. Authors concluded that due to the limited data available, there was insufficient evidence to support or refute the use of acupuncture for neuropathic pain in general, or for any specific neuropathic pain condition when compared with sham acupuncture or other active therapies. Yu et al. (2021) evaluated the clinical efficacy of acupuncture through a review and analysis of systematic reviews of acupuncture for the treatment of diabetic peripheral neuropathy. Eighty-eight reviews were retrieved. The inclusion criteria were a published systematic evaluation/meta-analysis/systematic review of acupuncture treatment for diabetic peripheral neuropathy, which included subjects meeting the diagnostic criteria for diabetic peripheral neuropathy, and which compared acupuncture treatment with non-acupuncture treatment. After the inclusion criteria had been applied, 18 reviews were finally included. Authors report that evidence shows that acupuncture improves diabetic peripheral neuropathy and increases nerve conduction velocity. However, the methodological quality of the reviews is generally extremely low, and most of the reviews had certain defects, showing that there is still much room for improvement in terms of the methodology and quality of the research reports.

8.7 Musculoskeletal and Pain Disorders of the Extremities

Green et al. (2008) reviewed the evidence for acupuncture for the treatment of shoulder pain in a 2008 Cochrane review. Nine trials of varying quality met the inclusion criteria. Acupuncture was found to improve shoulder function more than placebo at four weeks, but this benefit (a 3.53 point difference in a 100 point scale) was no longer considered clinical significant at four months. The authors concluded that there was insufficient evidence to either support or refute the use of acupuncture for shoulder pain.

Hinman et al. (2014) conducted a randomized clinical trial of acupuncture for knee pain. In total 282 patients, over 50 years of age, with chronic knee pain were randomized into one of four groups: 1. No treatment control; 2. Traditional needle acupuncture; 3. Laser acupuncture; 4. Sham laser (very low power). Subjects in the last three groups were treated once or twice a week for twelve weeks. Primary outcome measures were knee pain (0-10)

and function as measure by the McMaster Universities Osteoarthritis Index (0-68). End points were 12 weeks and one year. There was no difference in pain at twelve weeks between needle acupuncture or laser acupuncture and sham laser. There was a small difference between needle and laser treatment and the no treatment control at 12 weeks but not at one year. Needle acupuncture resulted in modest improvement in function compared with control at 12 weeks, but was not significantly different from sham and was not maintained at 1 year. The authors conclude, "In patients older than 50 years with moderate or severe chronic knee pain, neither laser nor needle demonstrate that acupuncture conferred benefit over sham for pain or function. Our findings do not support acupuncture for these patients."

Cox et al. (2016) assessed the effectiveness and safety of acupuncture therapies for musculoskeletal disorders of the extremities. The search revealed 5180 articles; 15 were included (10 with a low risk of bias, 5 with a high risk of bias). Authors concluded that the evidence for the effectiveness of acupuncture for musculoskeletal disorders of the extremities was inconsistent. Traditional needle acupuncture may be beneficial for CTS and Achilles tendinopathy, but not for nonspecific upper extremity pain and patellofemoral syndrome. Electroacupuncture may be effective for shoulder injuries and may show similar effectiveness to that of night wrist splinting for CTS. The effectiveness of dry needling for plantar fasciitis is equivocal. Leggit (2018) summarized the consensus on acupuncture as a musculoskeletal therapy. Evidence regarding efficacy in the management of musculoskeletal conditions is heterogeneous and subject to several limitations. Despite these limitations, acupuncture consistently has been shown to be more effective than no treatment and is relatively safe. For chronic back pain, it is recommended as a first-line noninvasive therapy. For neck pain, acupuncture provides benefits when it is combined with other treatments.

Babatunde et al. (2021) evaluated the comparative effectiveness of treatment options for relieving pain and improving function in patients with subacromial shoulder conditions (SSCs). The review identified 177 eligible trials. Current evidence shows small to moderate effect sizes for most treatment options for SSCs. Six treatments had a high probability of being most effective, in the short term, for pain and function [acupuncture, manual therapy, exercise, exercise plus manual therapy, laser therapy and Microcurrent (MENS) (TENS)], but with low certainty for most treatment options. After accounting for risk of bias, there is evidence of moderate certainty for the comparative effects of exercise on function in patients with SSCs. Future large, high-quality pragmatic randomised trials or meta-analyses are needed to better understand whether specific subgroups of patients respond better to some treatments than others.

8.8 Nausea and Vomiting

Ezzo et al. (2006) conducted a Cochrane Review on the effects of acupuncture point

stimulation for chemotherapy-induced nausea and vomiting. Eleven trials met the inclusion criteria. Different acupuncture modalities were used, and overall, acupuncture-point stimulation by all modalities reduced the incidence of acute vomiting, but not acute or delayed nausea severity compared to control. Electro-acupuncture reduced acute nausea, but manual acupuncture did not. Acupressure reduced acute nausea severity, but not acute vomiting or delayed nausea. Non-invasive electro-stimulation showed no benefits for any outcome. A more recent update of this review has been withdrawn for failure to complete on time.

A 2009 Cochrane Review (Lee and Fan, 2009) evaluated studies of the stimulation of wrist acupuncture point P6 for the prevention of postoperative nausea and vomiting. Forty trials were identified with 4858 individual subjects. Overall, acupuncture was found to be equally effective as anti-emetic drugs. This was true for both adults and children. It was also found equally effective whether using invasive needles or non-invasive stimulation of the acupuncture point.

Garcia et al. (2013) conducted a systematic review of the use of acupuncture in cancer care for the relief of multiple different symptoms. They identified 41 RCTs that met inclusion criteria. In total, eight different symptoms were evaluated: pain, nausea, hot flashes, fatigue, radiation-induced xerostomia, prolonged postoperative ileus, anxiety/mood disorders, and sleep disturbance. They found evidence that acupuncture was an effective treatment for nausea and vomiting, but the evidence was inconclusive or negative for the remaining symptoms.

Lee et al. (2013) conducted a clinical trial testing the effectiveness acupuncture to prevent opioid-induced nausea. They randomized 178 patients to one of three groups: 1. Pre-operative electro-acupuncture at P6; 2. Post-operative electro-acupuncture at P6; 3. A no-treatment control. The incidence of nausea and vomiting was significantly lower in the pre-operative group than in the control group. Vomiting was also lower in the pre-operative group than in the post-operative group. Overall, pre-operative, but not post-operative electro-acupuncture was more effective than the control group.

The effectiveness of acupuncture in preventing chemotherapy-related nausea and vomiting in patients with gynecological cancers was tested in a 2014 randomized clinical trial (Rithirangsriroj et al., 2014). Seventy patients were randomized to either acupuncture at P6 prior to chemotherapy infusion, or to the anti-emetic drug ondansetron. All patients received dexamethasone orally twice daily. The acupuncture group had a statistically significantly higher rate of complete absence of nausea and vomiting; 52.6% compared to 35.7% in the medication group. Overall, the acupuncture group had lower rates of nausea, less severe nausea and fewer side effects than the ondansetron group.

A second Cochrane Review (Matthews et al., 2015) evaluated a range of treatments, including acupuncture to treat nausea and vomiting in early pregnancy. Overall, the reviewers found that the low quality of evidence precluded any definitive conclusions. In addition, they noted that, "Acupuncture (P6 or traditional) showed no significant benefit to women in pregnancy."

Shen et al. (2015) completed a trial of 103 liver cancer patients tested the effectiveness of acupuncture at point K1 to prevent chemotherapy induced nausea and vomiting. Fifty-one patients were randomized to receive electrostimulation at K1 acupoint for twenty minutes prior to the first administration of chemotherapy and then daily for the next five days. They also received anti-emetic drugs. The control group underwent the same regimen except that they received electrostimulation at a presumed placebo point in their heel. Outcome measures included the rate, intensity and duration of nausea and frequency of vomiting. There were no significant differences between the two groups on any of the outcome measures.

Zhang et al. performed a meta-analysis (Zhang et al., 2015) on the use of wristband at acupuncture points for postoperative nausea and vomiting. They found a significant reduction in post-operative vomiting through the use of the wrist band compared to controls. However, they found no difference in the rates of nausea between wrist band and control.

Lu et al. (2021) explored acupuncture's clinical efficacy in treating hyperemesis gravidarum HG. A total of 16 trials covering 1043 gravidas were included. Compared with the conventional treatment, acupuncture had a significantly higher effective rate, a higher conversion rate of urine ketone, an improvement rate of nausea and vomiting, and a relatively higher improvement rate of food intake. Acupuncture also shortened hospitalization time and manifested with a lower pregnancy termination rate and fewer adverse events. Nevertheless, no statistical variation in the improvement of nausea intensity, vomiting episodes, and lassitude symptom, recurrence rate, and serum potassium was observed. Authors concluded suggested that acupuncture was effective in treating HG. However, as the potential inferior quality and underlying publication bias were found in the included studies, there is a need for more superior-quality RCTs to examine their effectiveness and safety.

References

American Medical Association. (current year). *Current Procedural Terminology (CPT) Current year* (rev. ed.). Chicago: AMA.

Atalay SG, Durmus A, Gezginaslan Ö. The Effect of Acupuncture and Physiotherapy on Patients with Knee Osteoarthritis: A Randomized Controlled Study. Pain Physician. 2021;24(3):E269-E278.

Babatunde OO, Ensor J, Littlewood C, et al. Comparative effectiveness of treatment options for subacromial shoulder conditions: a systematic review and network meta-analysis. Ther Adv Musculoskelet Dis. 2021;13:1759720X211037530. Published 2021 Sep 9.

Bannuru, R. R., McAlindon, T. E., Sullivan, M. C., Wong, J. B., Kent, D. M., & Schmid, C. H. (2015). Effectiveness and Implications of Alternative Placebo Treatments: A Systematic Review and Network Meta-analysis of Osteoarthritis Trials. *Annals of internal medicine*, *163*(5), 365–372. https://doi.org/10.7326/M15-0623

Casimiro, L., Barnsley, L., Brosseau, L., Milne, S., Robinson, V. A., Tugwell, P., & Wells, G. (2005). Acupuncture and electroacupuncture for the treatment of rheumatoid arthritis. *The Cochrane database of systematic reviews*, (4), CD003788. https://doi.org/10.1002/14651858.CD003788.pub2

Centers for Medicaid and Medicare Services (CMS) National Coverage Determinations (NCDs). NCD 30.3.3 Acupuncture for Chronic Lower Back Pain (cLBP). Retrieved on March 17, 2022 from https://www.cms.gov/medicare-coverage-database/details/ncd-details.aspx?NCDId=373

Centers for Medicaid and Medicare Services (CMS) National Coverage Determinations (NCDs). (2020). *Acupuncture.* NCD 30.3. Retrieved on March 17, 2022 from https://www.cms.gov/medicare-coverage-database/details/ncd-details.aspx?NCDId=11&ncdver=1&bc=AgAAQAAAAAAAAA%3D%3D&

Centers for Medicaid and Medicare Services (CMS) National Coverage Determinations (NCDs). NCD 30.3.1 Acupuncture for Fibromyalgia. Retrieved March 17, 2022 from https://www.cms.gov/medicare-coverage-database/details/ncd-details.aspx?NCDId=283

Centers for Medicaid and Medicare Services (CMS) National Coverage Determinations (NCDs). NCD 30.3.2 Acupuncture for Osteoarthritis. Retrieved March 17, 2022 from https://www.cms.gov/medicare-coverage-database/details/ncd-details.aspx?NCDId=284&ncdver=1&DocID=30.3.2&SearchType=Advanced&bc=IAAAABAAAAAA&

Centers for Medicaid and Medicare Services (CMS) Decision Memo for Acupuncture for Chronic Low Back Pain (CAG-00452N. Retrieved on March 17, 2022 from https://www.cms.gov/medicare-coverage-database/details/nca-decision-memo.aspx?NCAId=295

Chen, J., Tu, Q., Miao, S., Zhou, Z., & Hu, S. (2020). Transcutaneous electrical acupoint stimulation for preventing postoperative nausea and vomiting after general anesthesia: A meta-analysis of randomized controlled trials. *International journal of surgery (London, England), 73*, 57–64. https://doi.org/10.1016/j.ijsu.2019.10.036

Cherkin, D. C., Sherman, K. J., Deyo, R. A., & Shekell, P. G. (2003). A review of the evidence for the effectiveness, safety, and cost of acupuncture, massage therapy, and spinal manipulation for back pain. Annals of Internal Medicine, 138(11), 898-906.

Cho, Y. J., Song, Y. K., Cha, Y. Y., Shin, B. C., Shin, I. H., Park, H. J., Lee, H. S., Kim, K. W., Cho, J. H., Chung, W. S., Lee, J. H., & Song, M. Y. (2013). Acupuncture for chronic low back pain: a multicenter, randomized, patient-assessor blind, sham-controlled clinical trial. *Spine, 38*(7), 549–557. https://doi.org/10.1097/BRS.0b013e318275e601

Chou, R., Deyo, R., Friedly, J., Skelly, A., Hashimoto, R., Weimer, M., Fu, R., Dana, T., Kraegel, P., Griffin, J., Grusing, S., & Brodt, E. D. (2017). Nonpharmacologic Therapies for Low Back Pain: A Systematic Review for an American College of Physicians Clinical Practice Guideline. *Annals of internal medicine*, *166*(7), 493–505. https://doi.org/10.7326/M16-2459

Chou R, Deyo R, Friedly J, Skelly A, Hashimoto R, Weimer M, Fu R, Dana T, Kraegel P, Griffin J, Grusing S, Brodt E. Noninvasive Treatments for Low Back Pain. Comparative Effectiveness Review No. 169. (Prepared by the Pacific Northwest Evidence-based Practice Center under Contract No. 290-2012-00014-I.) AHRQ

Chou R and Hoyt Huffman LH. Nonpharmacologic therapies for acute and chronic low back pain: A review of the evidence for an American Pain Society/American College of Physicians Clinical Practice Guideline. Annals of Internal Medicine. 2007;147(7):492-504.

Chou R, Qaseem A, Snow V, Casey D, Cross JT Jr, Shekelle P, Owens DK; Clinical Efficacy Assessment Subcommittee of the American College of Physicians; American College of Physicians; American Pain Society Low Back Pain Guidelines Panel. Diagnosis and treatment of low back pain: a joint clinical practice guideline from the

American College of Physicians and the American Pain Society. Ann Intern Med. 2007 Oct 2;147(7):478-91.

Cox, J., Varatharajan, S., Côté, P., & Optima Collaboration (2016). Effectiveness of Acupuncture Therapies to Manage Musculoskeletal Disorders of the Extremities: A Systematic Review. *The Journal of orthopaedic and sports physical therapy*, *46*(6), 409–429. https://doi.org/10.2519/jospt.2016.6270

Crawford PF 3rd, Moss DA, Hawks MK, Snyder MJ. Integrative Medicine: Acupuncture. FP Essent. 2021;505:18-22.

Deare, J. C., Zheng, Z., Xue, C. C., Liu, J. P., Shang, J., Scott, S. W., & Littlejohn, G. (2013). Acupuncture for treating fibromyalgia. *The Cochrane database of systematic reviews*, *2013*(5), CD007070. https://doi.org/10.1002/14651858.CD007070.pub2

Deng, T. (1999). Practical Diagnosis in Traditional Chinese Medicine. Churchill Livingstone.

Ezzo, J. M., Richardson, M. A., Vickers, A., Allen, C., Dibble, S. L., Issell, B. F., Lao, L., Pearl, M., Ramirez, G., Roscoe, J., Shen, J., Shivnan, J. C., Streitberger, K., Treish, I., & Zhang, G. (2006). Acupuncture-point stimulation for chemotherapy-induced nausea or vomiting. *The Cochrane database of systematic reviews*, (2), CD002285. https://doi.org/10.1002/14651858.CD002285.pub2

Farag, A. M., Malacarne, A., Pagni, S. E., & Maloney, G. E. (2020). The effectiveness of acupuncture in the management of persistent regional myofascial head and neck pain: A systematic review and meta-analysis. *Complementary therapies in medicine*, *49*, 102297. https://doi.org/10.1016/j.ctim.2019.102297

Fu, C., Wu, T., Shu, Q., Song, A., & Jiao, Y. (2020). Acupuncture therapy on postoperative nausea and vomiting in abdominal operation: A Bayesian network meta analysis. *Medicine*, *99*(23), e20301. https://doi.org/10.1097/MD.0000000000020301

Furlan, A. D., van Tulder, M., Cherkin, D., Tsukayama, H., Lao, L., Koes, B., & Berman, B. (2005). Acupuncture and dry-needling for low back pain: an updated systematic review within the framework of the cochrane collaboration. *Spine*, *30*(8), 944–963. https://doi.org/10.1097/01.brs.0000158941.21571.01

Furlan, A. D., Yazdi, F., Tsertsvadze, A., Gross, A., Van Tulder, M., Santaguida, L., Cherkin, D., Gagnier, J., Ammendolia, C., Ansari, M. T., Ostermann, T., Dryden, T., Doucette, S., Skidmore, B., Daniel, R., Tsouros, S., Weeks, L., & Galipeau, J. (2010).

Complementary and alternative therapies for back pain II. *Evidence report/technology assessment*, (194), 1–764.

Garcia, M. K., McQuade, J., Haddad, R., Patel, S., Lee, R., Yang, P., Palmer, J. L., & Cohen, L. (2013). Systematic review of acupuncture in cancer care: a synthesis of the evidence. *Journal of clinical oncology : official journal of the American Society of Clinical Oncology*, *31*(7), 952–960. https://doi.org/10.1200/JCO.2012.43.5818

Ge L, Wang Q, He Y, et al. Acupuncture for cancer pain: an evidence-based clinical practice guideline. Chin Med. 2022;17(1):8. Published 2022 Jan 5. doi:10.1186/s13020-021-00558-4

Green, S., Buchbinder, R., Barnsley, L., Hall, S., White, M., Smidt, N., & Assendelft, W. (2002). Acupuncture for lateral elbow pain. *The Cochrane database of systematic reviews*, (1), CD003527. https://doi.org/10.1002/14651858.CD003527

Green, S., Buchbinder, R., & Hetrick, S. (2005). Acupuncture for shoulder pain. *The Cochrane database of systematic reviews*, (2), CD005319. https://doi.org/10.1002/14651858.CD005319

Griffiths, J. D., Gyte, G. M., Popham, P. A., Williams, K., Paranjothy, S., Broughton, H. K., Brown, H. C., & Thomas, J. (2021). Interventions for preventing nausea and vomiting in women undergoing regional anaesthesia for caesarean section. *The Cochrane database of systematic reviews*, *5*(5), CD007579. https://doi.org/10.1002/14651858.CD007579.pub3

Hinman, R. S., McCrory, P., Pirotta, M., Relf, I., Forbes, A., Crossley, K. M., Williamson, E., Kyriakides, M., Novy, K., Metcalf, B. R., Harris, A., Reddy, P., Conaghan, P. G., & Bennell, K. L. (2014). Acupuncture for chronic knee pain: a randomized clinical trial. *JAMA*, *312*(13), 1313–1322. https://doi.org/10.1001/jama.2014.12660

Hopton, A., & MacPherson, H. (2010). Acupuncture for chronic pain: is acupuncture more than an effective placebo? A systematic review of pooled data from meta-analyses. *Pain practice : the official journal of World Institute of Pain*, *10*(2), 94–102. https://doi.org/10.1111/j.1533-2500.2009.00337.x

Huang JF, Zheng XQ, Chen D, et al. Can Acupuncture Improve Chronic Spinal Pain? A Systematic Review and Meta-Analysis. Global Spine J. 2021;11(8):1248-1265. doi:10.1177/2192568220962440

Jin, Y., Wang, Y., Zhang, J., Xiao, X., & Zhang, Q. (2020). Efficacy and Safety of Acupuncture against Chemotherapy-Induced Peripheral Neuropathy: A Systematic Review and Meta-Analysis. *Evidence-based complementary and alternative medicine: eCAM*, *2020*, 8875433. https://doi.org/10.1155/2020/8875433

Ju, Z. Y., Wang, K., Cui, H. S., Yao, Y., Liu, S. M., Zhou, J., Chen, T. Y., & Xia, J. (2017). Acupuncture for neuropathic pain in adults. *The Cochrane database of systematic reviews*, *12*(12), CD012057. https://doi.org/10.1002/14651858.CD012057.pub2

Kim, T. H., Lee, M. S., Kim, K. H., Kang, J. W., Choi, T. Y., & Ernst, E. (2014). Acupuncture for treating acute ankle sprains in adults. *The Cochrane database of systematic reviews*, (6), CD009065. https://doi.org/10.1002/14651858.CD009065.pub2

Lam, M., Galvin, R., & Curry, P. (2013). Effectiveness of acupuncture for nonspecific chronic low back pain: a systematic review and meta-analysis. *Spine*, *38*(24), 2124–2138. https://doi.org/10.1097/01.brs.0000435025.65564.b7

Lee, A., & Fan, L. T. (2009). Stimulation of the wrist acupuncture point P6 for preventing postoperative nausea and vomiting. *The Cochrane database of systematic reviews*, (2), CD003281. https://doi.org/10.1002/14651858.CD003281.pub3

Lee, A., Chan, S. K., & Fan, L. T. (2015). Stimulation of the wrist acupuncture point PC6 for preventing postoperative nausea and vomiting. *The Cochrane database of systematic reviews*, *2015*(11), CD003281. https://doi.org/10.1002/14651858.CD003281.pub4

Lee, S., Lee, M. S., Choi, D. H., & Lee, S. K. (2013). Electroacupuncture on PC6 prevents opioid-induced nausea and vomiting after laparoscopic surgery. *Chinese journal of integrative medicine*, *19*(4), 277–281. https://doi.org/10.1007/s11655-013-1425-7

Leggit J. C. (2018). Musculoskeletal Therapies: Acupuncture, Dry Needling, Cupping. *FP essentials*, *470*, 27–31.

Li, Q. W., Yu, M. W., Wang, X. M., Yang, G. W., Wang, H., Zhang, C. X., Xue, N., Xu, W. R., Zhang, Y., Cheng, P. Y., Yang, L., Fu, Q., & Yang, Z. (2020). Efficacy of acupuncture in the prevention and treatment of chemotherapy-induced nausea and vomiting in patients with advanced cancer: a multi-center, single-blind, randomized, sham-controlled clinical research. *Chinese medicine*, *15*, 57. https://doi.org/10.1186/s13020-020-00333-x

Li, Y. X., Yuan, S. E., Jiang, J. Q., Li, H., & Wang, Y. J. (2020). Systematic review and meta-analysis of effects of acupuncture on pain and function in non-specific low back pain. *Acupuncture in medicine : journal of the British Medical Acupuncture Society*, *38*(4), 235–243. https://doi.org/10.1136/acupmed-2017-011622

Li H, Schlaeger JM, Jang MK, et al. Acupuncture Improves Multiple Treatment-Related Symptoms in Breast Cancer Survivors: A Systematic Review and Meta-Analysis. J Altern Complement Med. 2021;27(12):1084-1097. doi:10.1089/acm.2021.0133

Linde, K., Allais, G., Brinkhaus, B., Fei, Y., Mehring, M., Shin, B. C., Vickers, A., & White, A. R. (2016). Acupuncture for the prevention of tension-type headache. *The Cochrane database of systematic reviews*, *4*, CD007587. https://doi.org/10.1002/14651858.CD007587.pub2

Linde, K., Allais, G., Brinkhaus, B., Manheimer, E., Vickers, A., & White, A. R. (2009). Acupuncture for migraine prophylaxis. *The Cochrane database of systematic reviews*, (1), CD001218. https://doi.org/10.1002/14651858.CD001218.pub2

Linde, K., Allais, G., Brinkhaus, B., Manheimer, E., Vickers, A., & White, A. R. (2009). Acupuncture for tension-type headache. *The Cochrane database of systematic reviews*, (1), CD007587. https://doi.org/10.1002/14651858.CD007587

Liu, L., Skinner, M., McDonough, S., Mabire, L., & Baxter, G. D. (2015). Acupuncture for low back pain: an overview of systematic reviews. *Evidence-based complementary and alternative medicine : eCAM*, *2015*, 328196. https://doi.org/10.1155/2015/328196

Lu H, Zheng C, Zhong Y, Cheng L, Zhou Y. Effectiveness of Acupuncture in the Treatment of Hyperemesis Gravidarum: A Systematic Review and Meta-Analysis. Evid Based Complement Alternat Med. 2021;2021:2731446. Published 2021 Jul 27. doi:10.1155/2021/2731446

Maciocia, G. (2022). The Practice of Chinese Medicine (3rd ed.). Elsevier.

MacPherson, H., Maschino, A. C., Lewith, G., Foster, N. E., Witt, C. M., Vickers, A. J., & Acupuncture Trialists' Collaboration (2013). Characteristics of acupuncture treatment associated with outcome: an individual patient meta-analysis of 17,922 patients with chronic pain in randomised controlled trials. *PloS one*, *8*(10), e77438. https://doi.org/10.1371/journal.pone.0077438

MacPherson, H., Vertosick, E. A., Foster, N. E., Lewith, G., Linde, K., Sherman, K. J., Witt, C. M., Vickers, A. J., & Acupuncture Trialists' Collaboration (2017). The persistence of the effects of acupuncture after a course of treatment: a meta-analysis of

patients with chronic pain. *Pain, 158*(5), 784–793. https://doi.org/10.1097/j.pain.0000000000000747

Madsen, M. V., Gøtzsche, P. C., & Hróbjartsson, A. (2009). Acupuncture treatment for pain: systematic review of randomised clinical trials with acupuncture, placebo acupuncture, and no acupuncture groups. *BMJ (Clinical research ed.), 338*, a3115. https://doi.org/10.1136/bmj.a3115

Manheimer, E., Cheng, K., Linde, K., Lao, L., Yoo, J., Wieland, S., van der Windt, D. A., Berman, B. M., & Bouter, L. M. (2010). Acupuncture for peripheral joint osteoarthritis. *The Cochrane database of systematic reviews*, (1), CD001977. https://doi.org/10.1002/14651858.CD001977.pub2

Matthews, A., Haas, D. M., O'Mathúna, D. P., & Dowswell, T. (2015). Interventions for nausea and vomiting in early pregnancy. *The Cochrane database of systematic reviews*, *2015*(9), CD007575. https://doi.org/10.1002/14651858.CD007575.pub4

Mu J, Furlan AD, Lam WY, Hsu MY, Ning Z, Lao L. Acupuncture for chronic nonspecific low back pain. Cochrane Database Syst Rev. 2020;12(12):CD013814. Published 2020 Dec 11. doi:10.1002/14651858.CD013814

National Guideline Centre (UK). Evidence review for acupuncture for chronic primary pain: Chronic pain (primary and secondary) in over 16s: assessment of all chronic pain and management of chronic primary pain. London: National Institute for Health and Care Excellence (NICE); April 2021.

O'Connor, J., Bensky, D. (1996). Acupuncture: A Comprehensive Text. Eastland Press.

Paley CA, Johnson MI, Tashani OA, Bagnall AM. Acupuncture for cancer pain in adults. Cochrane Database Syst Rev. 2011 Jan 19;(1):CD007753.

Paley, C. A., Johnson, M. I., Tashani, O. A., & Bagnall, A. M. (2015). Acupuncture for cancer pain in adults. *The Cochrane database of systematic reviews*, *2015*(10), CD007753. https://doi.org/10.1002/14651858.CD007753.pub3

Qaseem, A., Wilt, T. J., McLean, R. M., Forciea, M. A., Clinical Guidelines Committee of the American College of Physicians, Denberg, T. D., Barry, M. J., Boyd, C., Chow, R. D., Fitterman, N., Harris, R. P., Humphrey, L. L., & Vijan, S. (2017). Noninvasive Treatments for Acute, Subacute, and Chronic Low Back Pain: A Clinical Practice Guideline From the American College of Physicians. *Annals of internal medicine*, *166*(7), 514–530. https://doi.org/10.7326/M16-2367

Rithirangsriroj, K., Manchana, T., & Akkayagorn, L. (2015). Efficacy of acupuncture in prevention of delayed chemotherapy induced nausea and vomiting in gynecologic cancer patients. *Gynecologic oncology*, *136*(1), 82–86. https://doi.org/10.1016/j.ygyno.2014.10.025

Saragiotto BT, Maher CG, Yamato TP, Costa LO, Menezes Costa LC, Ostelo RW, Macedo LG. Motor control exercise for chronic non-specific low-back pain. Cochrane Database Syst Rev. 2016 Jan 8;(1):CD012004.

Shekelle P. Diagnosis and Treatment of Low Back Pain: A Joint Clinical Practice Guideline from the American College of Physicians and the American Pain Society. What's New? What's Different? Retrieved on February 9, 2021 from https://www.guideline.gov/expert/expert-commentary.aspx?id=16452&search=chiropractic.

Shen, Y., Liu, L., Chiang, J. S., Meng, Z., Garcia, M. K., Chen, Z., Peng, H., Bei, W., Zhao, Q., Spelman, A. R., & Cohen, L. (2015). Randomized, placebo-controlled trial of K1 acupoint acustimulation to prevent cisplatin-induced or oxaliplatin-induced nausea. *Cancer*, *121*(1), 84–92. https://doi.org/10.1002/cncr.28973

Skelly, A. C., Chou, R., Dettori, J. R., Turner, J. A., Friedly, J. L., Rundell, S. D., Fu, R., Brodt, E. D., Wasson, N., Winter, C., & Ferguson, A. (2018). *Noninvasive Nonpharmacological Treatment for Chronic Pain: A Systematic Review*. Agency for Healthcare Research and Quality (US).

Smith, C. A., Zhu, X., He, L., & Song, J. (2011). Acupuncture for primary dysmenorrhoea. *The Cochrane database of systematic reviews*, (1), CD007854. https://doi.org/10.1002/14651858.CD007854.pub2

Sridharan, K., & Sivaramakrishnan, G. (2020). Interventions for treating hyperemesis gravidarum: a network meta-analysis of randomized clinical trials. *The journal of maternal-fetal & neonatal medicine : the official journal of the European Association of Perinatal Medicine, the Federation of Asia and Oceania Perinatal Societies, the International Society of Perinatal Obstetricians*, *33*(8), 1405–1411. https://doi.org/10.1080/14767058.2018.1519540

Su X, Qian H, Chen B, et al. Acupuncture for acute low back pain: a systematic review and meta-analysis. Ann Palliat Med. 2021;10(4):3924-3936.

Tice JA, Kumar V, Otuonye I, et al. Cognitive and Mind-Body Therapies for Chronic Low Back and Neck Pain: Effectiveness and Value, Final Evidence Report, November 6,

2017. The Institute for Clinical and Economic Review (ICER), prepared for the California Technology Assessment Forum. Retrieved on March 17, 2022 from https://icer.org/wp-content/uploads/2020/10/CTAF_LBNP_Final_Evidence_Report_110617.pdf

Tick, H., & Nielsen, A. (2019). Academic Consortium for Integrative Medicine & Health Commentary to Health and Human Services (HHS) on Inter-agency Task Force Pain Management Best Practices Draft Report. *Global advances in health and medicine*, *8*, 2164956119857656. https://doi.org/10.1177/2164956119857656

Trinh, K. V., Graham, N., Gross, A. R., Goldsmith, C. H., Wang, E., Cameron, I. D., Kay, T., & Cervical Overview Group (2006). Acupuncture for neck disorders. *The Cochrane database of systematic reviews*, (3), CD004870. https://doi.org/10.1002/14651858.CD004870.pub3

Turkistani A, Shah A, Jose AM, et al. Effectiveness of Manual Therapy and Acupuncture in Tension-Type Headache: A Systematic Review. Cureus. 2021;13(8):e17601. Published 2021 Aug 31.

U.S. Department of Health and Human Services (2019, May). Pain Management Best Practices Inter-Agency Task Force Report: Updates, Gaps, Inconsistencies, and Recommendations. Retrieved from U. S. Department of Health and Human Services website: https://www.hhs.gov/ash/advisory-committees/pain/reports/index.html

Van Hal M, Dydyk AM, Green MS. Acupuncture. In: StatPearls. Treasure Island (FL): StatPearls Publishing; July 31, 2021.

van Middelkoop M, Rubinstein SM, Verhagen AP, Ostelo RW, Koes BW, van TulderMW. Exercise therapy for chronic nonspecific low-back pain. Best Pract Res Clin Rheumatol. 2010 Apr;24(2):193-204.

van Tulder M, Becker A, Bekkering T, Breen A, del Real MT, Hutchinson A, Koes B, Laerum E, Malmivaara A; COST B13 Working Group on Guidelines for the Management of Acute Low Back Pain in Primary Care. Chapter 3. European guidelines for the management of acute nonspecific low back pain in primary care. Eur Spine J. 2006 Mar;15 Suppl 2:S169-91.

Vickers AJ1, Cronin AM, Maschino AC, Lewith G, MacPherson H, Foster NE, Sherman KJ, Witt CM, Linde K; Acupuncture Trialists' Collaboration. Acupuncture for chronic pain: individual patient data meta-analysis. Arch Intern Med. 2012 Oct 22;172(19):1444-53.

Walsh NE, Brooks P, Hazes JM, et al. Standards of care for acute and chronic musculoskeletal pain: The bone and joint decade (2000-2010). Arch Phys Med Rehabil. 2008;89:1830-1845.

Wang L, Yin Z, Zhang Y, Yu Y, Lin Y, Zhao L. Optimal Acupuncture Methods for Nonspecific Low Back Pain: A Systematic Review and Bayesian Network Meta-Analysis of Randomized Controlled Trials Journal of Pain Research. 2021:14, 1097-1112.

Washington State Department of Labor and Industries. Conservative care options for work-related mechanical shoulder conditions. Olympia (WA): Washington State Department of Labor and Industries; 2014 Apr 17. 31 p. Retrieved on February 9, 2021 from https://www.guidelinecentral.com/summaries/conservative-care-options-for-work-related-mechanical-shoulder-conditions/#section-420

Wong JJ, Côté P, Sutton DA, et al. Clinical practice guidelines for the noninvasive management of low back pain: A systematic review by the Ontario Protocol for Traffic Injury Management (OPTIMa) Collaboration. Eur J Pain. 2017;21(2):201-216.

Wu B, Yang L, Fu C, et al. Efficacy and safety of acupuncture in treating acute low back pain: a systematic review and bayesian network meta-analysis. Ann Palliat Med. 2021;10(6):6156-6167.

Xiang Y, He J, Li R. Appropriateness of sham or placebo acupuncture for randomized controlled trials of acupuncture for nonspecific low back pain: a systematic review and meta-analysis. J Pain Res. 2017 (11):83-94.

Xiang Y, He J, Tian H, Cao B, Li R. Evidence of efficacy of acupuncture in the management of low back pain: a systematic review and meta-analysis of randomised placebo- or sham-controlled trials. Acupunct Med. 2020 Feb;38(1):15-24.

Xinnong C. (2019). Chinese Acupuncture and Moxibustion (3rd ed.). Foreign Languages Press.

Xiong Q, Min S, Wei K, Yang Y, Ma J, Liu D. Transcutaneous Electrical Acupoint Stimulation Combined with Dexamethasone and Tropisetron Prevents Postoperative Nausea and Vomiting in Female Patients Undergoing Laparoscopic Sleeve Gastrectomy: a Prospective, Randomized Controlled Trial. Obes Surg. 2021 May;31(5):1912-1920.

Yang J, Wahner-Roedler DL, Zhou X, et al. Acupuncture for palliative cancer pain management: systematic review. BMJ Support Palliat Care. 2021;11(3):264-270.

Yu B, Li M, Huang H, et al. Acupuncture treatment of diabetic peripheral neuropathy: An overview of systematic reviews. J Clin Pharm Ther. 2021;46(3):585-598.

Yuan Q, Guo T, Liu L, Sun F, Zhang Y. Traditional Chinese medicine for neck pain and low back pain: a systematic review and meta-analysis. PLoS One. 2015; 10(2):e0117146.

Zeng Y and Chung JW. Acupuncture for chronic nonspecific low back pain: An overview of systematic reviews. European Journal of Integrative Medicine. 2015; 7(2): 94-107.

Zhang GL1, Yang SY1, Zhu ZL1, Mu PX1. Meta-analysis on postoperative complications of wristband acupoint pressure therapy. J Biol Regul Homeost Agents. 2015 Jan-Mar;29(1):187-93.

Zhang Y, Zhang C, Yan M, Wang N, Liu J, Wu A. The effectiveness of PC6 acupuncture in the prevention of postoperative nausea and vomiting in children: A systematic review and meta-analysis. Paediatr Anaesth. 2020 May;30(5):552-563.

Zhang Y, Sun Y, Li D, et al. Acupuncture for Breast Cancer: A Systematic Review and Meta-Analysis of Patient-Reported Outcomes. Front Oncol. 2021;11:646315. Published 2021 Jun 10. doi:10.3389/fonc.2021.646315